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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No. S2004/0368

Date of Filing 25 May 2004

Applicant CHRISTY CUMMINS an Irish citizen of 9 Furnes Manor, Johnstown, Naas, Co. Kildare, and JAMES E. COLEMAN, of 20 Greenmount Road, Terenure, Dublin 6.

Dated this 31 day of May 2005.

Colerel
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S 040356

FORM NO. 1

**REQUEST FOR THE GRANT OF A PATENT
PATENTS ACT, 1992**

The Applicant named herein hereby request

the grant of a patent under Part II of the Act

the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. APPLICANTS

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Description Nationality: 1. An Irish Citizen

2. An Irish Citizen

2. TITLE OF INVENTION

"Surgical Stapler"

3. DECLARATION OF PRIORITY ON BASIS OF PREVIOUSLY FILED APPLICATION FOR SAME INVENTION (SECTIONS 25 & 26)

Previous filing date

Country in or for
which filed

Filing No.

NONE.

4. IDENTIFICATION OF INVENTOR(S)

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5. STATEMENT OF RIGHT TO BE GRANTED A PATENT (SECTION 17(2)(B))

By virtue of the Applicants being the Inventors

6. ITEMS ACCOMPANYING THIS REQUEST - TICK AS APPROPRIATE

- (i) prescribed filing fee (€60.00)
- (ii) specification containing a description and claims
 - specification containing a description only
 - Drawings referred to in description or claims
- (iii) An abstract
- (iv) Copy of previous application(s) whose priority is claimed
- (v) Translation of previous application whose priority is claimed
- (vi) Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. DIVISIONAL APPLICATION

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No:

Filing Date:

8. **AGENT**

The following is authorised to act as agent in all proceedings connected with the obtaining of a Patent to which this request relates and in relation to any patent granted -

Name
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at their address as recorded for the time being in
the Register of Patent Agents

9. **ADDRESS FOR SERVICE (IF DIFFERENT FROM THAT AT 8)**

CUMMINS, Christy
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F. R. KELLY & CO.

By:


EXECUTIVE

Date: May 25, 2004

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SURGICAL STAPLER

S 040368

FIELD OF THE INVENTION

[0001] The present invention relates to methods and devices for closing a puncture wound in a liquid carrying vessel.

BACKGROUND OF THE INVENTION

[0002] A variety of surgical procedures require a puncture wound to be formed in a liquid carrying vessel, and upon completion of the procedure, the puncture wound must be closed in order to prevent loss of blood through the puncture hole. In certain cases, the wound can be closed by maintaining external pressure over the vessel until the puncture naturally seals. This procedure can take approximately 30 minutes with the length of time usually being greater if the patient is hypertensive or anticoagulated. The procedure can also be uncomfortable for the patient and involves costly professional time on the part of the hospital staff. Other pressure techniques such as pressure bandages, sandbags or clamps have been employed but these also involve ensuring the patient remains motionless for an extended period of time and is monitored to ensure the effectiveness of the procedure. Accordingly, a number of devices have been developed which provide an obstruction in the area of the puncture in order to prevent bleeding.

[0003] Such devices include, for example, collagen plugs which, when placed at the blood vessel opening, absorb body fluids, swell and affect a seal. Some plug like devices utilize an anchor that is positioned inside the vessel and a collagen plug that is positioned outside the vessel, thereby sandwiching the puncture to effect a closure. Surgical staples, clips, and other devices have also been used to close puncture wounds.

[0004] While these devices are typically effective, there remains a need for improved methods and devices for closing a puncture in a liquid-carrying vessel by stapling.

SUMMARY OF THE INVENTION

[0005] The present invention generally provides methods and devices for closing a puncture wound in a liquid carrying vessel. In one exemplary embodiment, a surgical stapler is provided having a locator tube having proximal and distal ends with an inflation lumen extending through at least a portion thereof, and an inflatable member, such as an inflatable balloon, formed proximal to the distal end of the locator tube and in communication with the inflation lumen. The inflatable member is movable between a deflated position and an inflated position. The device also includes a staple applying apparatus that is slidably disposed on a portion of the locator tube proximal to the inflatable member. The staple applying apparatus is adapted to apply a surgical staple to seal a puncture wound in a liquid carrying vessel. The device can also include a guidewire entry port formed in the distal end of the locator tube, and a guidewire exit port formed in a sidewall of the locator tube at a location distal to the inflatable member.

[0006] The staple applying apparatus can have a variety of configurations, but in one embodiment it includes a sheath having a staple pusher slidably disposed therein and adapted to push a staple against an anvil disposed within a distal end of the staple applying apparatus, and a staple former slidably disposed around the staple pusher and the anvil and adapted to deform a staple. The sheath can have a distal end that is expandable from a closed position, in which the sheath is adapted to be deployed through a tissue tract, and an open position, in which the sheath is retracted relative to the staple pusher, staple former, and anvil. More preferably, the distal end of the sheath includes opposed cut-out portions formed therein to allow the sheath to move between the open and closed positions. The staple applying apparatus also preferably includes at least one staple having a central portion with an opening formed therein and disposed around the locator tube, and opposed legs extending distally from opposed ends of the central portion. In use, when the staple is pushed against the anvil by the staple pusher, the anvil is adapted to engage a portion of the opposed legs of the staple to move the legs a distance apart from one another such that the staple is adapted to be deployed into a liquid carrying vessel.

[0007] In other embodiments, the device can include a pressure relief valve coupled to the inflation lumen in the locator tube and adapted to regulate a pressure within the inflatable member. The device can also optionally include a position indicator formed on or in the locator

tube that is effective to indicate a position of the inflatable member relative to a liquid carrying vessel. The position indicator can be, for example, a lumen extending through the locator tube and having a distal, blood inlet port formed adjacent to the inflatable member, and a proximal, blood outlet port. The blood inlet port is preferably formed just proximal to the inflatable member such that the inlet port will be positioned external to a liquid carrying vessel when the inflatable member is inflated and positioned against an internal surface of a liquid carrying vessel adjacent puncture wound.

[0008] In other embodiments of the present invention, a method for closing a puncture wound in a liquid carrying vessel is provided. The method includes the step of positioning an inflatable member within a liquid carrying vessel such that the inflatable member abuts a puncture wound formed in the vessel. In an exemplary embodiment, the inflatable member is positioned over a guidewire that is predisposed within the liquid carrying vessel. The method further includes the steps of positioning a distal end of a staple applying apparatus adjacent the puncture wound against an external surface of the liquid carrying vessel, deploying a surgical staple into the liquid carrying vessel such that the staple extends across the puncture wound, deflating the inflatable member and removing the locator tube from the liquid carrying vessel, and deforming the staple to close the puncture wound in the liquid carrying vessel. Prior to the step of positioning an inflatable member within a liquid carrying vessel, a locator tube can be advanced along a tissue tract through a puncture wound in a liquid carrying vessel to position a distal portion of the tube having the inflatable member formed thereon within the liquid carrying vessel. After the locator tube is advanced to position the inflatable member on the distal portion of the tube within the liquid carrying vessel, an external blood signal can be used to indicate the correct position of the inflatable member within the vessel. The inflatable member is preferably inflated and the locator tube is retracted until the inflatable member abuts the puncture wound in the liquid carrying vessel. Blood flow through a blood flow lumen formed on the locator tube can be used to indicate a position of the inflatable member relative to the liquid carrying vessel. Blood flowing preferably ceases when the inflatable member is positioned within the liquid carrying vessel and abuts the puncture wound internally.

[0009] In other aspects, the method can include, prior to the step of deploying a surgical staple, advancing a staple applying apparatus containing the surgical staple along a proximal portion of

the locator tube to position a distal end of the staple applying apparatus at the puncture wound adjacent an external surface of the liquid carrying vessel. The staple applying apparatus preferably includes a sheath having a staple pusher slidably disposed therein, an anvil disposed distal of the pusher, and a staple former slidably disposed around the staple pusher and the anvil. In order to deploy the staple, the staple pusher is preferably advanced distally to push the staple against the anvil whereby the staple is moved to an open position. The staple is then further advanced distally to deploy opposed legs of the staple into the liquid carrying vessel. The step of deforming the staple can include the step of advancing the staple former further distally to deform the opposed legs of the staple around the anvil toward one another into a closed position. In yet another embodiment of the present invention, a method for closing a puncture wound in a liquid carrying vessel is provided and includes the steps of advancing a locator tube along a tissue tract through a puncture wound in a liquid carrying vessel to position a distal portion of the tube having an inflatable member formed thereon within the liquid carrying blood vessel, inflating the inflatable member on the locator tube, retracting the locator tube until the inflatable member abuts the puncture wound in the liquid carrying vessel, advancing a staple applying apparatus along a proximal portion of the locator tube to position a distal end of the staple applying apparatus at the puncture wound adjacent an external surface of the liquid carrying vessel, deploying a surgical staple into the liquid carrying vessel such that the staple extends across the puncture wound, deflating the inflatable member and removing the locator tube from the liquid carrying vessel, and deforming the staple to close the puncture wound in the liquid carrying vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0011] FIG. 1 is a perspective view of one embodiment of a surgical stapler having a staple applying apparatus slidably disposed around a locator tube in accordance with the present invention;

[0012] FIG. 2 is a perspective view of one embodiment of a staple in an open configuration according to the invention;

[0013] FIG. 3 is a perspective view of the staple shown in FIG. 2 in a closed configuration;

[0014] FIG. 4 is a perspective view of an alternative embodiment of a staple in a closed, pre-deployed configuration according to the invention;

[0015] FIG. 5 is a perspective view of a portion of the staple applying apparatus shown in FIG. 1 having a sheath shown in a retracted position disposed around a former which is disposed around an anvil, and a surgical staple positioned between the anvil at a distal end of the former and around the locator tube, the apparatus being in a pre-deployed position;

[0016] FIG. 6 is a perspective view of the staple applying apparatus shown in FIG. 5 with the staple advanced by a pusher disposed in the former into an open position in which the staple is ready to be deployed;

[0017] FIG. 7 is a perspective view of the staple applying apparatus shown in FIG. 6 with an inflatable member the locator in an inflated position, and with the staple partially deformed and ready to be fully-deployed;

[0018] FIG. 8 is a perspective view of the staple applying apparatus shown in FIG. 7 with the locator tube removed, and with the staple fully deformed into a closed configuration;

[0019] FIG. 9 is a perspective view of the staple applying apparatus shown in FIG. 8 with the former withdrawn and the anvil open to release the staple;

[0020] FIG. 10 is a perspective view of the staple applying apparatus shown in FIG. 9 with the staple released and the staple applying apparatus in the post-fire condition;

[0021] FIG. 11 is a side view of the staple applying apparatus shown in FIG. 1;

[0022] FIG. 12 is a side perspective view of the handle housing of the staple applying apparatus shown in FIG. 11 with the right side of the trigger and the right side of the handle housing removed;

[0023] FIG. 13 is a side view of the staple applying apparatus shown in FIG. 12 advanced over the locator tube;

[0024] FIG. 14 is a cross-sectional view illustration of a distal portion of the locator tube shown in FIGS. 1 and 13;

[0025] FIG. 15 is a side, partially cross-sectional view of method for using the surgical stapler of FIG. 1, showing the locator tube disposed around a guidewire and having a deflated balloon positioned outside an arterial lumen;

[0026] FIG. 16 is a side, partially cross-sectional view of the locator tube shown in FIG. 15 with the deflated balloon positioned inside the arterial lumen;

[0027] FIG. 17 is a side, partially cross-sectional view of the locator tube shown in FIG. 16 with the balloon inflated within the arterial lumen, and having the distal end of the staple applying apparatus shown in FIG. 1 positioned at the arterial puncture site;

[0028] FIG. 18 is a side, partially cross-sectional view of the locator tube and staple applying apparatus shown in FIG. 17 with the sheath and former withdrawn to expose the staple;

[0029] FIG. 19 is a side view of the staple applying apparatus shown in FIG. 11 with the sheath lever activated;

[0030] FIG. 20 is a side view of the staple applying apparatus shown in FIG. 19 with the trigger semi-deployed;

[0031] FIG. 21 is a side, partially cross-sectional perspective view of the locator tube and apparatus shown in FIG. 18 with the open staple penetrated into the arterial wall;

[0032] FIG. 22 is a side, partially cross-sectional perspective view of the locator tube and apparatus shown in FIG. 21 with the locator tube withdrawn and the staple deformed and deployed into the arterial wall to close the puncture;

[0033] FIG. 23 is a side view of the staple applying apparatus shown in FIG. 20 with the locator tube fully withdrawn;

[0034] FIG. 24 is a side view of the staple applying apparatus shown in FIG. 23 with the trigger fully deployed;

[0035] FIG. 25 is a side, partially cross-sectional perspective view of the staple applying apparatus shown in FIG. 22 showing the staple being released from the apparatus; and

[0036] FIG. 26 is a side, partially cross-sectional perspective view of the locator tube and apparatus shown in FIG. 25 showing the staple positioned in the arterial wall.

DETAILED DESCRIPTION OF THE INVENTION

[0037] The present invention provides methods and devices for closing a puncture wound in a liquid carrying vessel. In one exemplary embodiment, shown in FIG. 1, a surgical stapler 10 is provided having a staple applying apparatus 12 that is slidably disposed around a locator tube 14. The locator tube 14 includes an inflatable member 16 formed thereon proximal to the distal end 14b thereof, and in use the inflatable member 16 is effective to locate a puncture wound in a liquid carrying vessel. In particular, the distal end 14b of the locator tube 14 can be inserted through a puncture wound in a vessel to position the inflatable member 16 within the vessel. The inflatable member 16 can then be inflated, and the locator tube 14 can be retracted until the inflatable member 16 abuts the internal surface of the vessel adjacent to the puncture wound. The staple applying apparatus 12 can then be moved along the locator tube 14 to position it against the external surface of the vessel adjacent the puncture wound, whereby a staple can be applied to close the puncture.

[0038] At the outset, to facilitate understanding of the invention, it is necessary to describe an exemplary staple for using with the staple applying apparatus. A person skilled in the art will appreciate, however, that staples having a variety of shapes, sizes, and configurations can be used with the present invention. Referring to FIGS. 2-4, an exemplary staple 100 is shown and it is generally substantially U-shape and includes a base 102 with a loop section 104 and a pair of generally Y-shaped legs 106, 108 extending substantially perpendicularly from opposite ends 102a, 102b of the base 102. FIG. 2 illustrates the staple 100 in an open and ready to deploy configuration, in which the legs 106, 108 of the open staple 100 are bent approximately 90° relative to the base 102, and FIG. 3 illustrates the staple 100 in a closed configuration, in which the legs 106, 108 are bent toward one another. Figure 4 shows an alternative embodiment for the closed post-deployed staple 100' where the loop section 104' has been changed in shape. To effect a greater compression of stapled tissue, the legs 106, 108, 106', 108' can include a

penetrative portion 106a, 106b, 108a, 108b, 106a', 106b', 108a', 108b' adjacent the tip and a compressive structure 106c, 108c, 106c', 108c', which due to its increased height relative to that of the penetrative portion, spreads the compressive forces of the staple 100, 100' further along the length of the incision being closed. The compressive portion 106c, 108c, 106c', 108c' also provides a depth stop to avoid the tip 106a, 106b, 108a, 108b, 106a', 106b', 108a', 108b' penetrating too deeply into the tissue in which it is deployed. The staple 100, 100' is described in more detail in U.S. Publication No. 2004/0028502 entitled "Surgical Staple," filed on January 22, 2003, and incorporated herein by reference in its entirety. A person skilled in the art will appreciate that the staple can have a variety of configurations, and moreover that the staple can be formed from a variety of materials. In an exemplary embodiment, the staple is bioabsorbable, and more preferably, by way of non-limiting example, the staple is formed from a magnesium alloy.

[0039] Referring back to FIG. 1, the staple applying apparatus 12 can have a variety of configurations, but it is preferably adapted to apply a surgical staple to seal a puncture wound in a liquid carrying vessel. In an exemplary embodiment, the staple applying apparatus 12 includes a handle housing 18 having a substantially rigid cylindrical shaft 20 extending therefrom. The cylindrical shaft 20 includes a staple opening and deployment mechanism 24 (FIGS. 5-10) for deploying a surgical staple to close a puncture wound, and the housing 18 includes components that are effective to actuate the staple opening and deployment mechanism 24.

[0040] The cylindrical shaft 20 is shown in more detail in FIGS. 5-10, and as shown, the shaft 20 is preferably formed from several cylindrical components. The outermost cylinder is a sheath 22, which preferably extends along the full length of the shaft 20. The sheath 22 is adapted to be disposed around the staple opening and deployment mechanism 24 during insertion of the device 12. Accordingly, while the shape and size of the sheath 22 can vary, in an exemplary embodiment the distal end 22b of the sheath 22 has an outer diameter d_s (FIG. 5) that reduces at a distal-most end, preferably from approximately 4 mm to approximately 1.5 mm, which is the same as the outside diameter d_l of the locator tube 13. Such a transition provides a smooth and blended profile for non-traumatic dilation of subcutaneous tissue during percutaneous insertion. Once the sheath 22 has been inserted through percutaneous tissue, it can be retracted to expose the staple opening and deployment mechanism 24. Thus, in order to facilitate retraction of the

sheath 22, a distal end 22b of the sheath 22 can be splittable, and more particularly the sheath 22 can include one or more slits or openings formed therein that allow the distal end to spread apart when the sheath is retracted. In an exemplary embodiment, as shown in FIG. 5, the sheath 22 includes opposed slits 22c (only one opening is shown) that extend from the distal end 22b thereof and that have an enlarged proximal region 22d to prevent cracking or breaking of the sheath 22 as the sheath 22 is retracted. The slits 22c can vary in shape and size, but they should allow the sheath 22 to be retracted a sufficient distance to allow the staple opening and deployment mechanism 24 to be exposed.

[0041] Inside the sheath 22 is the staple opening and deployment mechanism 24, which includes a former component 26, a pusher 30, and an anvil 28. The former 26 extends cylindrically from the handle 18 to the distal tip 20b of the shaft 20 (FIG. 1), i.e., the distal tip 22b of the sheath 22, and it is preferably a generally elongate, cylindrical member that is used to protect the staple 100 in its pre-deployed position and secondly to close the staple 100 by deforming it against the anvil 28 that also extends from the handle 18 to the distal tip 20b of the shaft 20. The anvil 28 can vary in shape and size, but preferably it has a cylindrical shape with a distal end that is split axially to form two generally semicircular-sectioned extensions 28a₁, 28b₁. The extensions 28a₁, 28b₁ can each extend outward from the cylindrical body of the anvil 28, and can include a second portion 28a₂, 28b₂ that extends back inward toward the body 28 to form a tang, as shown in FIG. 5. The surface of the staple 100 will rest primarily against the tangs 28a₂, 28b₂ during the staple opening and closing processes, which will be discussed in more detailed below.

[0042] As noted above, the staple opening and deployment mechanism 24 also includes a pusher 30 that is disposed within the former 26, as shown in FIGS. 6, 9 and 10, and that is effective to advance the staple 100 toward the anvil 28 to deform the staple 100 from a pre-deployed, closed configuration (FIG. 3) to an open configuration (FIG. 2). In particular, the pusher 30 advances the staple 100 against the anvil tangs 28a₂, 28b₂ causing the arms 106, 108 of the staple 100 to deform into their open configuration. The pusher 30 also holds the staple 100 in position during deformation of the staple arms 106, 108 as the staple 100 is being closed, which can be achieved by moving the former 26 distally toward the anvil 28, thereby causing the legs 106, 108 to close. The pusher 30 further houses the locator tube 14, which extends from the proximal end 18b of

the handle 18 (FIG. 1) through the shaft 20 and forward of the distal end 20b of the shaft 20. The locator tube 14 will be discussed in more detail below.

[0043] As previously mentioned, the shaft 20 extends from the handle housing 18, which contains components that are effective to actuate the staple opening and deployment mechanism 24. As shown in FIGS. 11-13, the handle housing 18 generally includes a sheath lever 32 that is effective to retract the sheath 22 to expose the staple opening and deployment mechanism 24, thus allowing a surgical staple 100 to be deployed into a vessel. Accordingly, the sheath lever 32 is attached to the proximal end (not shown) of the splittable sheath 22. The sheath 22 can, however, be retracted by a trigger 34 formed on the handle housing 18. The trigger 34 preferably has tracks 34a, 34b, 34c, 34d which engage with cylindrical pins 36a, 36b, 36c, 36d (FIG. 12) that extend from cylindrical bushes (only three bushes 38b, 38c, 38d are shown) formed on the proximal end (not shown) of the splittable sheath 22, the proximal end 26a of the former 26, the proximal end 28a of the anvil 28, and the proximal end 30a of the pusher 30, respectively. In use, the trigger 34 is effective to activate the pusher 30 to advance a staple 100 along the locator tube 14 until it comes into contact with the anvil 28, at which point the legs 106, 108 of the staple 100 are moved into an open position. The trigger 34, upon further activation, is also effective to move the staple 100 distally to penetrate a vessel, and then to move the former 26 distally to deform the staple 100 into a closed position, thereby closing a puncture wound in a vessel. The handle housing 18 is also effective to slidably receive the locator tube 14, which extends into the distal end 18b of the housing 18 and connects to a hub 40 formed on the proximal end 18a of the housing 18. The proximal end 18a, in turn, is connected to a movable flange 42 which, when disconnected from the handle 18, allows the locator tube 14 to be removed from the housing 18.

[0044] An exemplary embodiment of a locator tube 14 for use with the surgical stapler 12 is shown in detail in FIG. 14, which illustrates the distal portion of the locator tube 14. The locator tube 14 can have a variety of shapes and sizes, but it preferably has a generally elongate cylindrical shape with one or more lumens extending therethrough between proximal and distal ends (only distal end 14b is shown in FIG. 14) thereof. In the illustrated embodiment, the locator tube 14 is formed from an outer tube 42 and an inner tube 44. The inner tube 44 extends distally beyond the outer tube 42, and it includes an inflation lumen 44a extending therethrough and

having a side hole 44c that is in communication with an inflatable member, such as a balloon 16 as shown, for delivering fluid to the inflatable member 16. The inflatable member 16 is preferably disposed on the inner tube 44 at a location that is proximal to the distal end 44b thereof. The inflation lumen 44a terminates proximal to the distal end 44b of the inner tube 44 to prevent fluid flowing therethrough from exiting the locator tube 14. The inflation lumen 44a can also include a core wire 46 extending therethrough and adapted to add rigidity and stiffness to the tube 14.

[0045] The outer tube 42, which is disposed around the inner tube 44, terminates proximal to the inflatable member 16, and it also defines a lumen 42a extending therethrough. The lumen 42a in the outer tube 42, however, is configured to receive blood flow therethrough for indicating a position of the inflatable member 16. In particular, a blood entry port 42c is formed in the outer tube 42 adjacent the distal end 42b thereof for allowing blood to flow through lumen 42a in the outer tube 42, e.g., within a channel formed between the outer tube 42 and the inner tube 44. The lumen/channel 42a extends to a blood exit port 42d (shown in FIG. 16) that is formed in the outer tube 42 at a location that is just distal to the distal end 22b of the shaft 22 of the staple applying apparatus 12. As a result, when the locator tube 14 is positioned within a blood vessel, blood can flow into the blood entry port 42c, through the lumen/channel 42a, and out the blood exit port 42d to indicate that the locator tube 14, and in particular the inflatable member 16, is positioned within the blood vessel. The blood exit port 42d is also preferably positioned such that, when the inflatable member 16 is inflated and the locator tube 14 is retracted until the inflatable member 16 abuts the inner surface of the blood vessel, the blood exit port 42d is located outside of the blood vessel. As a result, blood will not flow through the lumen/channel 42a indicating that the inflatable member 16 is properly positioned within the blood vessel against the puncture wound.

[0046] In another embodiment, the locator tube 14 can include a guide lumen 48 extending therethrough for receiving a guide wire 50. While the guide lumen 48 can be formed at a variety of locations on the locator tube 14, in the embodiment shown in FIG. 14, the guide lumen 48 is formed from a single lumen tube that extends from the distal end 44b of the inner tube 44 of the locator tube 14 and that includes an open distal tip 48a (FIG. 15) and a side hole 48b formed at the proximal end thereof. In use, a guide wire 50 can be placed through the single lumen tube 48

to guide the locator tube 14 through a puncture and into a blood vessel, as will be discussed in more detail below.

[0047] As previously indicated and shown in FIGS. 11-13, the proximal end 14a of the locator tube 14 is connected to the hub 40 formed on the proximal end 18a of the handle housing 18. The hub 40 can be attached to the proximal end 18a, and one or more rigid guide tubes 45a and 45b can extend from the proximal end 18a and through the flange 42 and the handle 18. Once the proximal end 18a is disconnected from the flange 42, which is connected to the handle 18, it is held in position and the handle 18 is advanced along the guide tube(s) 45a and 45b and locator tube 14 until notches 47a and 47b at the distal end of the tube(s) engage with pins 49a and 49b within the handle 18 which are propelled by springs into these notches.

[0048] Referring to FIGS. 1 and 11, in order to inflate the inflatable member 16, a syringe 54 can be coupled to the hub 40 to deliver fluid and/or gas to the inflatable member 16 to cause it to expand from a closed position to an open position. A stop cock 56 can also be formed on the hub 40 to open and close fluid flow through the hub 40, and a pressure relief valve 58 can be coupled to the hub 40 for regulating the pressure within the inflatable member 16. In an exemplary embodiment, the pressure relief valve 58 allows leakage to occur once a predetermined pressure, such as 4 Bar, has been achieved in the inflatable member 16.

[0049] FIGS. 15-26 illustrate the surgical stapler 10 in use. In general, once an investigational or therapeutic procedure has been completed a guidewire 50 which is positioned within the artery 80 and extends through the arterial puncture hole 82, the tissue tract 84 and skin puncture 86, will be left in position. Referring to FIG. 15, the locator tube 14, and in particular the guidewire tube 48 that forms the distal portion of the locator tube 14, is advanced over the exposed proximal tip 50a of the guidewire 50 until the guidewire 50 exits the locator tube 14 through the guidewire exit hole 48b formed in the wall of the guidewire tube 48 on the distal side of the balloon 16. The locator tube 14 continues to be advanced along the guidewire 50 through the puncture hole 86 in the skin, through the tissue tract 84 and through the puncture hole 82 in the artery 80 and into the arterial lumen 80a. Advancing the locator tube 14 along the guidewire 50 will stop when the guidewire exit hole 48b aligns with the skin puncture, as shown. At this point the guidewire 50 may be removed and discarded. The locator tube 14 preferably has a length

that is sufficient to ensure that the locator tube 14 enters the artery 80 prior to removal of the guidewire 50. The locator tube 14, and more particularly the guidewire tube 48 portion of the locator tube 14, also preferably has sufficient stiffness and/or rigidity to guide the locator tube 14 into the artery, in the absence of the guidewire 50, until the blood entry hole 42c positioned on the proximal side of the balloon 16 enters the arterial lumen 80a causing blood to enter and travel in a proximal direction through the lumen 42a until it exits at the blood signal hole 42d, as shown in FIG. 16. This signal confirms correct position of the balloon 16 within the arterial lumen 80a.

[0050] As shown in FIG. 17, the balloon 16 is then inflated. In particular, the syringe 54 containing fluid is connected to the hub 40, via the pressure relief valve and stopcock. The stopcock 56 is turned to its open position, and fluid is injected into the locator tube 14 and balloon 16 until the pressure relief valve 58 indicates that the correct balloon pressure has been reached. Leakage preferably occurs at the pressure valve 58 once a maximum pressure, e.g., 4 Bar, has been reached. At this point the stopcock 56 is turned to a closed position thereby ensuring that the balloon 16 remains inflated. The handle 18 to which the locator tube 14 is attached is moved back causing the locator tube 14 and the inflated balloon 16 to move back intra-arterially towards the puncture hole 82. When the balloon 16 reaches the puncture hole 82, resistance will be felt as the balloon 16 cannot travel any further, signalling the correct position of the balloon 16. In addition the balloon 16 can act as a tamponade ensuring a reduction in blood loss through the puncture hole 82.

[0051] If the balloon 16 is correctly located against the endo-arterial surface at the puncture site 82, the blood inlet hole 42c will be external to the artery 80 and the signalling will have ceased, confirming the correct location of the balloon 16. Adversely, if resistance to withdrawing the balloon 16 is felt and the signal continues, this will indicate that the balloon 16 may be falsely anchored within the artery lumen 80a and is incorrectly positioned.

[0052] At this point the shaft 20 must be advanced along the locator tube 14 to a point where the distal tip 20b of the shaft 20 is juxtaposition on the arterial puncture hole 82, as is also shown in FIG. 17. This is done by releasing the proximal end 18a at the proximal end of the handle 18, holding it in a fixed position and advancing the handle 18 and rigid shaft 20 distally along the rigid guide tube(s) 45a and 45b and the locator tube 14 until the handle 18 locks into a

predefined position onto the rigid tube(s) 45a and 45b and will advance no further. The handle 18 preferably advances along locator tube 14 and rigid guide tube(s) 45a and 45b slide rails until rail lock pins 49a and 49b engage with notches 47a and 47b in the guide tube preventing the handle 18 from moving forward any further. When fully advanced, the distal tip 22b of the sheath 22 is preferably positioned about 3 mm to 10 mm back from the proximal surface of the balloon 16. This allows space for the opening of the staple 100 with minimal risk of damage to the artery 80 at the puncture site 82 due to contact with the moving staple legs 106, 108.

[0053] Prior to opening and deployment of the staple 100, the splittable sheath 22 must be withdrawn and the former 26 retracted to expose the staple 100 as shown in Figure 18. Activation of the trigger 34 is not possible until the sheath lever 32 is back to its stopped position. Pulling back on the sheath lever 32, in a direction indicated by the arrow shown in FIG. 19, retracts the splittable sheath 22. This has the effect of pulling the reduced diameter section of the sheath 22 against the cylindrical profile of the former 26. As a result, the sheath 22 splits at the distal tip and is retracted over the former 26. The former 26 and sheath 22 are further retracted together so as to expose the anvil 28 and the staple 100, which is in a pre-deployed configuration such that the locator tube 14 extends through the cylindrical base 102 and the legs 106, 108 are bent inward toward one another.

[0054] The trigger 32 is then advanced to a first stop, as shown in FIG. 20. During this movement of the trigger 32, the pins 36a, 36b, 36c, 36d that extend from the cylindrical bush (only bushes 38b, 38c, and 38d are shown in FIG. 12) that is attached to the proximal end of the former 26, anvil 28, and pusher 30 engage with tracks 34a, 34b, 34c, 34d that are cut into each side of the handle assembly 18 (FIGS. 12 and 20). The shape of each track 34a, 34b, 34c, 34d with which the pins 36a, 36b, 36c, 36d engage dictates the axial movement of the cylindrical bush (38b, 38c, 38d in FIG. 12) to which the pins 36a, 36b, 36c, 36d are attached. During this part of the cycle the pusher 30 is advanced forward to open the staple 100, as shown in FIG. 21. In particular, the pusher 30 has advanced the loop 104 of the staple 100 forward so that the arms 106, 108 of the staple 100 firstly abut the anvil tangs 28a, 28b then cause the arms 106, 108 of the staple 100 to bend outward thus displacing the staple legs 106, 108 away from each other and away from the locator tube 14. As the staple arms 106, 108 bend open they engage with slots (not shown) in the former 26 so as to ensure they remain in correct alignment. Opening of the

staple 100 continues until the staple legs 106, 108 are approximately 90 degrees to the staple base 102 or loop 104. Once the staple 100 is fully open the trigger 34 on the handle 18 continues to advance. A latch 51 (FIG 1) at the proximal end of the trigger 34 is released allowing a compression spring 43 (FIG. 12) to push the moveable flange 42, that is attached to the proximal end 18a which is attached to the locator tube 14, in a proximal direction. This in turn causes the balloon 16 and staple 100 to advance toward each other until the staple legs 106, 108 have punctured the arterial wall 80. As the trigger 34 continues to be advanced the former 26 is moved forward against the staple arms 106, 108 causing them to be deformed around the anvil tangs 28a, 28b and the staple legs 106, 108 to bend and move toward each other. The staple 100 is now in a semi-deployed configuration and attached to the wall of the artery 80, as shown in FIG. 22. Once the staple 100 has been partially deformed toward its closed position, the trigger 34 reaches a mechanical stop and remains in the first, partially activated position shown in FIG. 20. A mechanical interlock 35 (Fig 12) prevents any further advancement until the locator tube 14 has been withdrawn from the artery 80 through the shaft 20 and handle 18.

[0055] The locator tube 14 is withdrawn after deflating the balloon 16. This is done by turning the stopcock 56 to an open position and using the syringe 54 to deflate the balloon 16. Once deflated the stopcock 56 is turned back to the closed position or to a locked position, and the locator tube hub 40 is disconnected from the proximal end 18a on the proximal end of the handle housing 18. The locator tube 14 is fully withdrawn from the artery 80 and the device 12, as shown in FIGS. 22 and 23. Alternatively, the moveable flange 42, which is now engaged with the handle 18, may be disengaged and removed. As the locator tube 14 is attached to the slide assembly via the hub 40 at the proximal end 18a it will also be fully withdrawn from the device 12.

[0056] Once the locator tube 14 is withdrawn from the device 12, the trigger interlock 35 disengages allowing the trigger 34 to be advanced further. The trigger 34 may then be fully deployed, as shown in Figure 24, causing the former 26 to advance fully over the staple 100 while the pusher 30 is moving back simultaneously to form it to its closed position around the puncture hole 82 so as to effect closure of the puncture wound 82. Such a technique also reduces the applied stress on the staple material, and it achieves a staple configuration with a tighter and stronger closure.

[0057] Once closed, the former 26 and sheath 22 are both retracted to a position that allows the anvil arms 28 to spring outward thereby disengaging the anvil tangs 28a, 28b from the staple 100. A compression spring 37 (FIG. 12) pushing against the former bush 38b is used to drive the former 26 back causing the anvil arms 28 to spread open and disengage from the staple 100, as shown in FIGS. 25 and 26. Alternatively, the anvil 28 can be rotated 90 degrees so as to disengage the tangs 28a, 28b from the staple 100, and the former 26 and sheath 22 are retracted until the anvil arms 28 can deflect outward so that the staple 100 is free of the device 12. In both cases the pusher 30 may be used to apply a forward force to the staple 100 so that upon withdrawal of the anvil tangs 28a, 28b the staple 100 is advanced forward of the anvil 28. The device 12 may then be withdrawn from the tissue tract 84 and discarded. Prior to withdrawal of the device 12 from the tissue tract 84, the former 26 may be advanced over the anvil 28 causing the anvil arms to bend inward within the former 26 and thereby reducing the effective diameter of the deployment mechanism to be withdrawn through the subcuticular tissue.

[0058] One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

[0059] What is claimed is:

CLAIMS:

1. A surgical stapler for closing a puncture wound in a liquid carrying vessel, comprising:
 - a locator tube having proximal and distal ends with an inflation lumen extending through at least a portion thereof;
 - an inflatable member formed proximal to the distal end of the locator tube and in communication with the inflation lumen, the inflatable member being movable between a deflated position and an inflated position; and
 - a staple applying apparatus slidably disposed on a portion of the locator tube proximal to the inflatable member, the staple applying apparatus being adapted to apply a surgical staple to seal a puncture wound in a liquid carrying vessel.
2. The surgical stapler of claim 1, further comprising a guidewire entry port formed in the distal end of the locator tube, and a guidewire exit port formed in a sidewall of the locator tube at a location distal to the inflatable member.
3. The surgical stapler of claim 1, wherein the inflatable member comprises an inflatable balloon.
4. The surgical stapler of claim 1, wherein the staple applying apparatus includes a sheath having a staple pusher slidably disposed therein and adapted to push a staple against an anvil disposed within a distal end of the staple applying apparatus, and a staple former slidably disposed around the staple pusher and the anvil and adapted to deform a staple.
5. The surgical stapler of claim 4, wherein the sheath has a distal end that is expandable from a closed position, in which the sheath is adapted to be deployed through a tissue tract, and an open position, in which the sheath is retracted relative to the staple pusher, staple former, and anvil.
6. The surgical stapler of claim 5, wherein the distal end of the sheath includes opposed cut-out portions formed therein to allow the sheath to move between the open and closed positions.

7. The surgical stapler of claim 4, further comprising at least one staple having a central portion with an opening formed therein and disposed around the locator tube, and opposed legs extending distally from opposed ends of the central portion.

8. The surgical stapler of claim 7, wherein, when the staple is pushed against the anvil by the staple pusher, the anvil is adapted to move the legs a distance apart from one another such that the staple is adapted to be deployed into a liquid carrying vessel.

9. The surgical stapler of claim 7, wherein the at least one staple is bioabsorbable.

10. The surgical stapler of claim 9, wherein the at least one staple is formed from a magnesium alloy.

11. The surgical stapler of claim 1, further comprising a pressure relief valve coupled to the inflation lumen in the locator tube and adapted to regulate a pressure within the inflatable member.

12. The surgical stapler of claim 1, wherein the locator tube includes a position indicator that is effective to indicate a position of the inflatable member relative to a liquid carrying vessel.

13. The surgical stapler of claim 12, wherein the position indicator comprises a lumen extending through the locator tube and having a distal, blood inlet port formed adjacent to the inflatable member, and a proximal, blood outlet port.

14. The surgical stapler of claim 13, wherein the blood inlet port is formed just proximal to the inflatable member such that the inlet port will be positioned external to a liquid carrying vessel when the inflatable member is positioned against an internal surface of a liquid carrying vessel adjacent puncture wound.

15. A method for closing a puncture wound in a liquid carrying vessel, comprising: positioning an inflatable member within a liquid carrying vessel such that the inflatable

member abuts an internal wall of the vessel adjacent a puncture wound;
positioning a distal end of a staple applying apparatus adjacent the puncture wound against an external surface of the liquid carrying vessel;
deploying a surgical staple into the liquid carrying vessel such that the staple extends across the puncture wound;
deflating the inflatable member and removing the locator tube from the liquid carrying vessel; and
deforming the staple to close the puncture wound in the liquid carrying vessel.

16. The method of claim 15, further comprising, prior to the step of positioning an inflatable member within a liquid carrying vessel, advancing a locator tube along a tissue tract through a puncture wound in a liquid carrying vessel to position a distal portion of the tube having the inflatable member formed thereon within the liquid carrying vessel.

17. The method of claim 16, wherein, after the locator tube is advanced to position the inflatable member on the distal portion of the tube within the liquid carrying vessel, the inflatable member is inflated and the locator tube is retracted until the inflatable member abuts the puncture wound in the liquid carrying vessel.

18. The method of claim 16, wherein the locator tube includes a blood flow lumen extending therethrough for receiving blood flow from the liquid carrying vessel to indicate a position of the inflatable member relative to the liquid carrying vessel.

19. The method of claim 18, wherein blood flowing from a proximal end of the locator tube is effective to indicate that the inflatable member is positioned within the liquid carrying vessel.

20. The method of claim 18, wherein, when the inflatable member is inflated and the locator tube is retracted until the inflatable member abuts the puncture wound in the liquid carrying vessel, blood flow from the proximal end of the locator tube ceases to indicate proper positioning of the inflatable member.

21. The method of claim 17, further comprising, prior to the step of deploying a surgical staple, advancing a staple applying apparatus containing the surgical staple along a proximal portion of the locator tube to position a distal end of the staple applying apparatus at the puncture wound adjacent an external surface of the liquid carrying vessel.

22. The method of claim 21, wherein the staple applying apparatus includes a sheath having a staple pusher slidably disposed therein, an anvil disposed distal of the pusher, and a staple former slidably disposed around the staple pusher and the anvil.

23. The method of claim 22, wherein the step of deploying the staple comprises the steps of retracting the sheath, advancing the staple pusher distally to push the staple against the anvil whereby the staple is moved to an open position, and advancing the staple distally to deploy opposed legs of the staple into the liquid carrying vessel.

24. The method of claim 23, wherein the step of deforming the staple comprises the step of advancing the staple former further distally to deform the opposed legs of the staple around the anvil toward one another into a closed position.

25. The method of claim 23, wherein the step of deforming the staple comprises moving the staple former in a forward direction and the pusher in a reverse direction to progressively deform the opposed legs of the staple around the anvil toward one another into a closed position.

26. The method of claim 23, wherein the sheath is in a closed position, such that the sheath surrounds the staple pusher, anvil, staple former, and staple, when the staple applying apparatus is advanced along the locator tube, and wherein the sheath moves to an open position when the sheath is retracted to deploy the staple.

27. The method of claim 16, wherein the inflatable member is formed on the locator tube proximal to a distal end of the locator tube.

28. The method of claim 16, wherein the locator tube is advanced along a guide wire that is pre-positioned along the tissue tract through the puncture wound in the liquid carrying vessel.

29. The method of claim 28, wherein the locator tube includes a guidewire inlet port formed in a distal end thereof, and a guidewire outlet port formed proximal to the distal end.

30. The method of claim 29, wherein the guidewire outlet port is formed distal of the inflatable member.

31. The method of claim 15, wherein the inflatable member is coupled to a pressure relief valve that is adapted to regulate a pressure within the inflatable member.

32. A method for closing a puncture wound in a liquid carrying vessel, comprising the steps of:

- advancing a locator tube along a tissue tract through a puncture wound in a liquid carrying vessel to position a distal portion of the tube having an inflatable member formed thereon within the liquid carrying blood vessel;
- inflating the inflatable member on the locator tube;
- retracting the locator tube until the inflatable member abuts the puncture wound in the liquid carrying vessel;
- advancing a staple applying apparatus along a proximal portion of the locator tube to position a distal end of the staple applying apparatus at the puncture wound adjacent an external surface of the liquid carrying vessel;
- deploying a surgical staple into the liquid carrying vessel such that the staple extends across the puncture wound;
- deflating the inflatable member and removing the locator tube from the liquid carrying vessel; and
- deforming the staple to close the puncture wound in the liquid carrying vessel.

33. The method of claim 32, wherein the locator tube is advanced along a guide wire that is pre-positioned along the tissue tract through the puncture wound in the liquid carrying vessel.

34. The method of claim 33, wherein the locator tube includes a guidewire inlet port formed in a distal end thereof, and a guidewire outlet port formed proximal to the distal end.

35. The method of claim 34, wherein the guidewire outlet port is formed distal of the inflatable member.

ABSTRACT OF THE DISCLOSURE

Methods and devices for closing a puncture wound in a liquid carrying vessel are provided. In one exemplary embodiment, a surgical stapler is provided having a locator tube with an inflatable member formed thereon and adapted to be positioned within a liquid carrying vessel adjacent a puncture wound, and a staple applying apparatus that is slidably disposed on a portion of the locator tube and that is adapted to apply a surgical staple to seal a puncture wound in a liquid carrying vessel.

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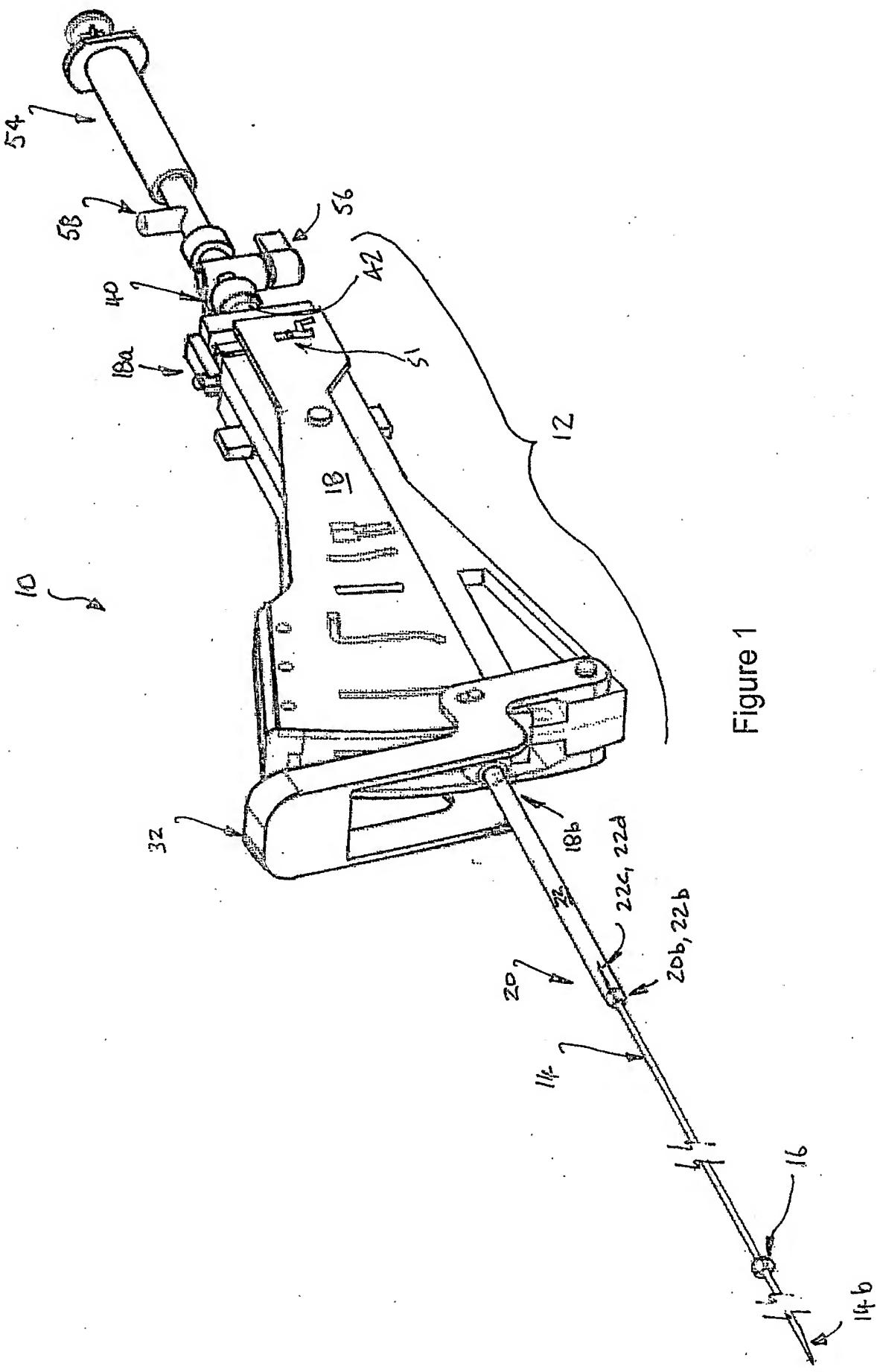


Figure 1

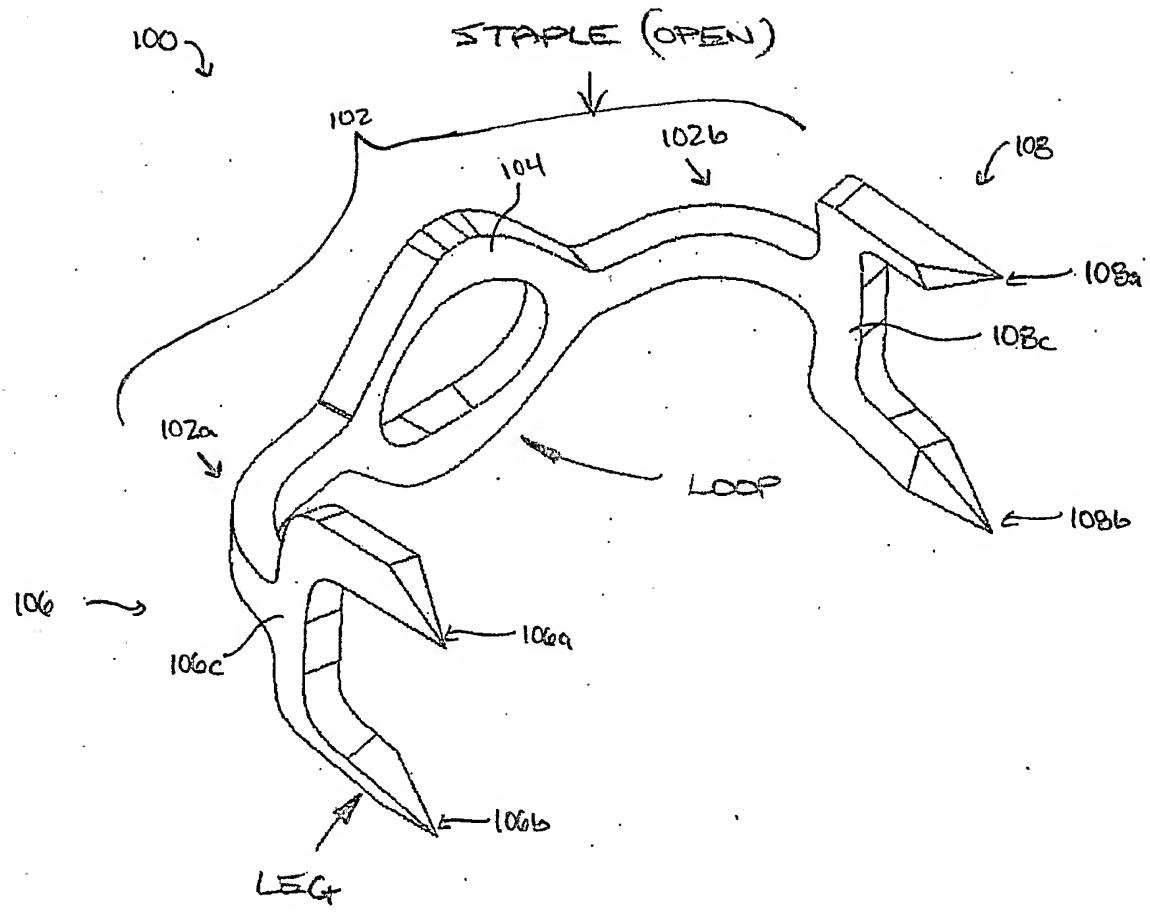


FIG 2

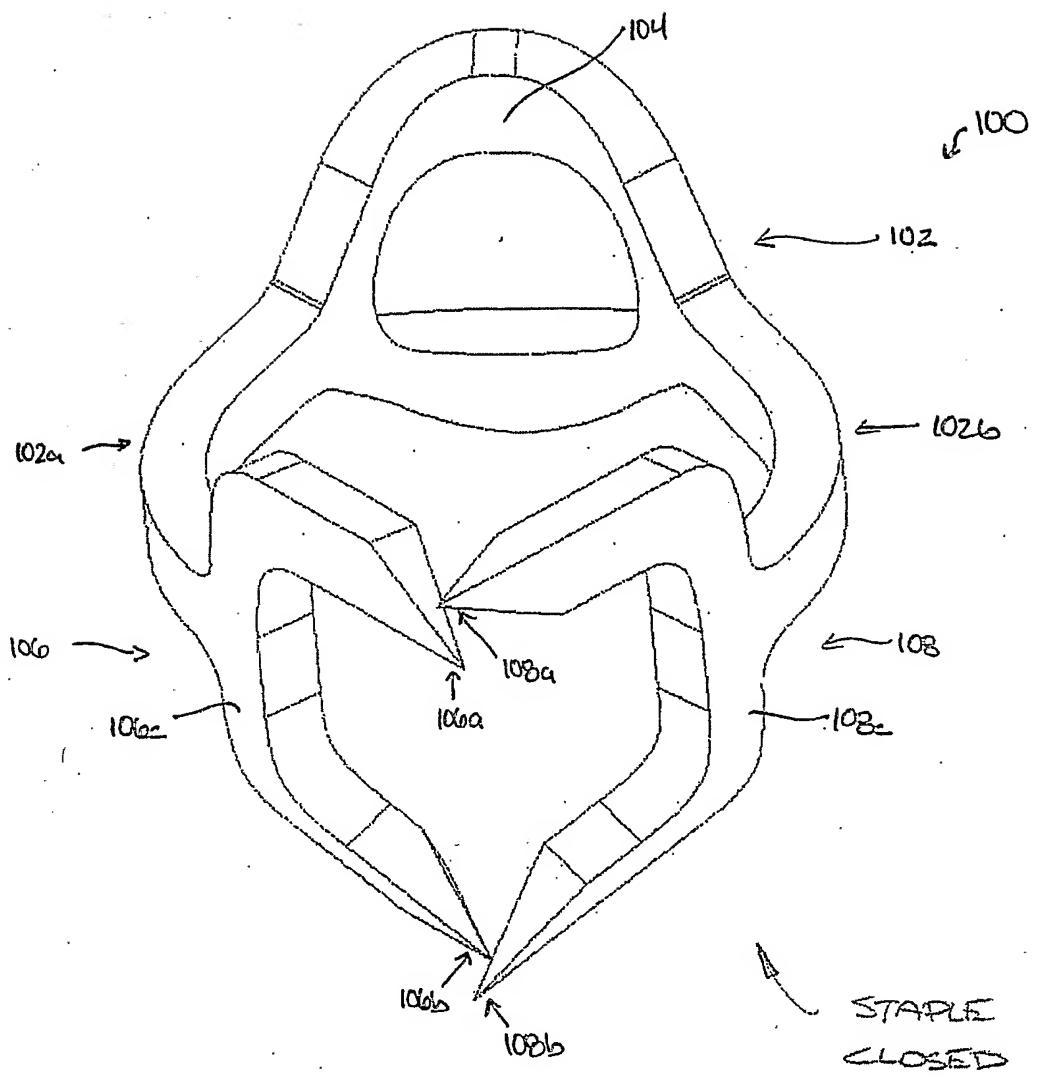


FIG. 3

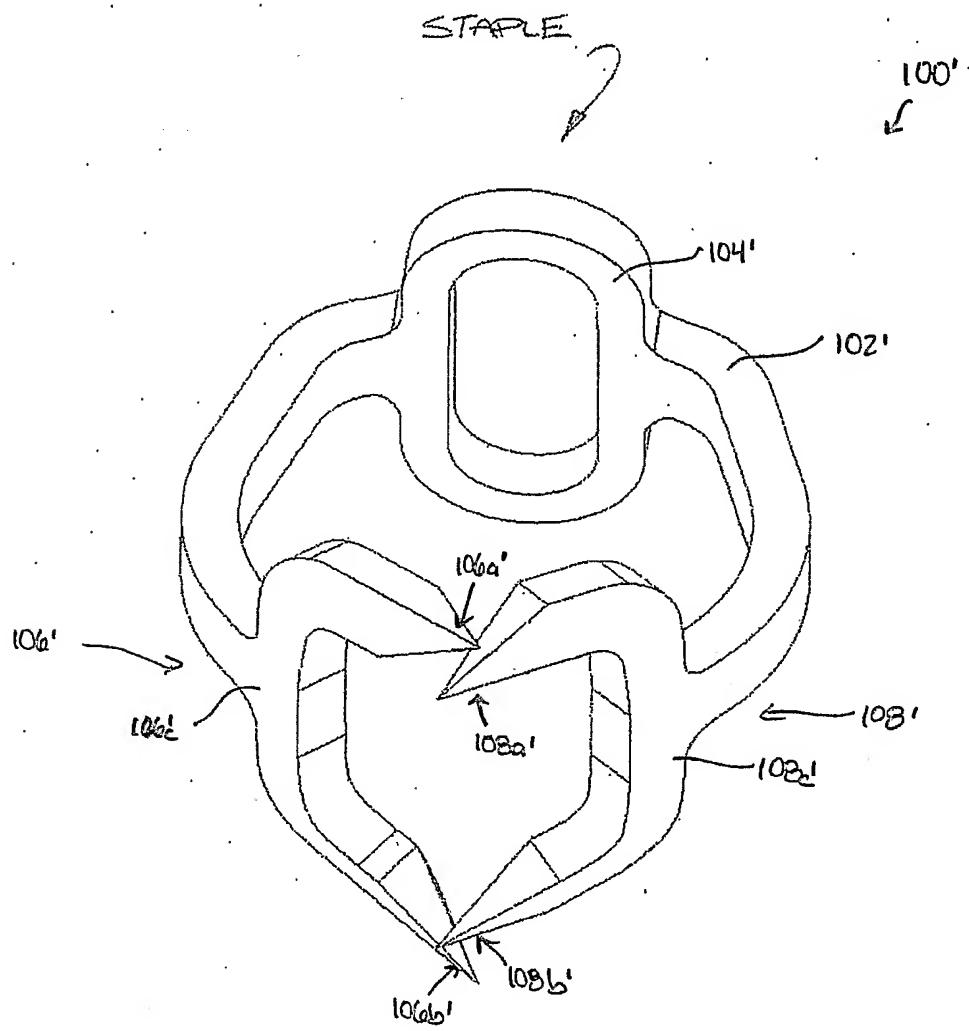


FIG. 4

20

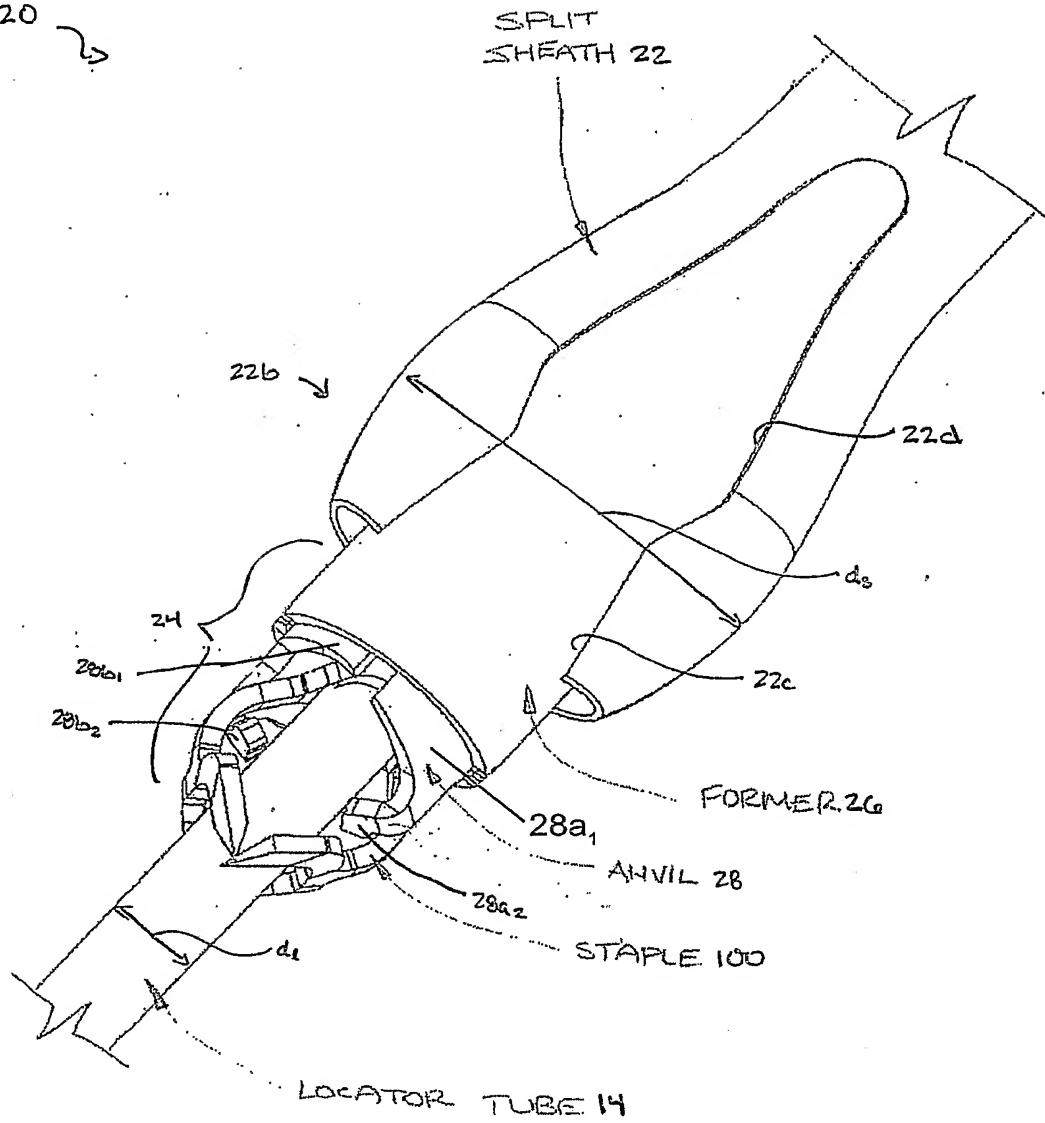


FIG 5

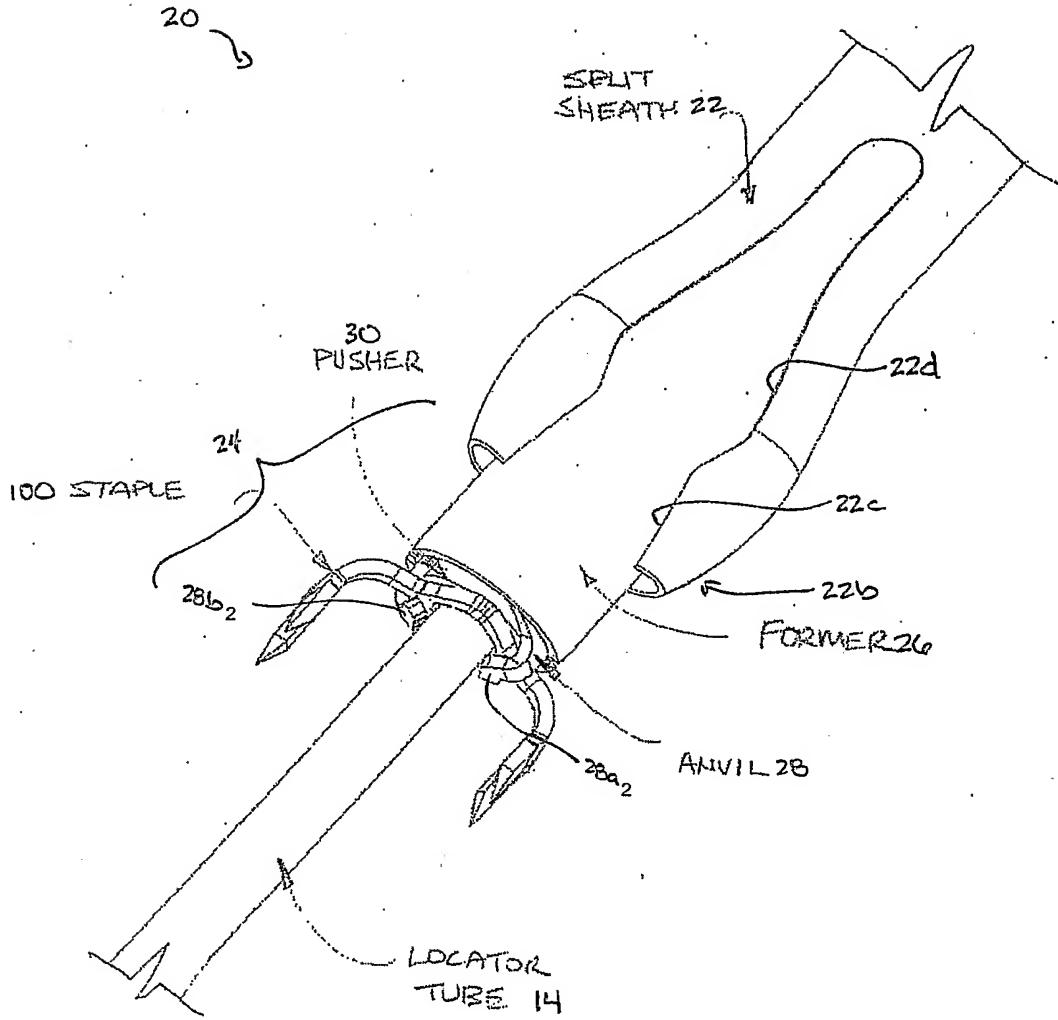


FIG. 6

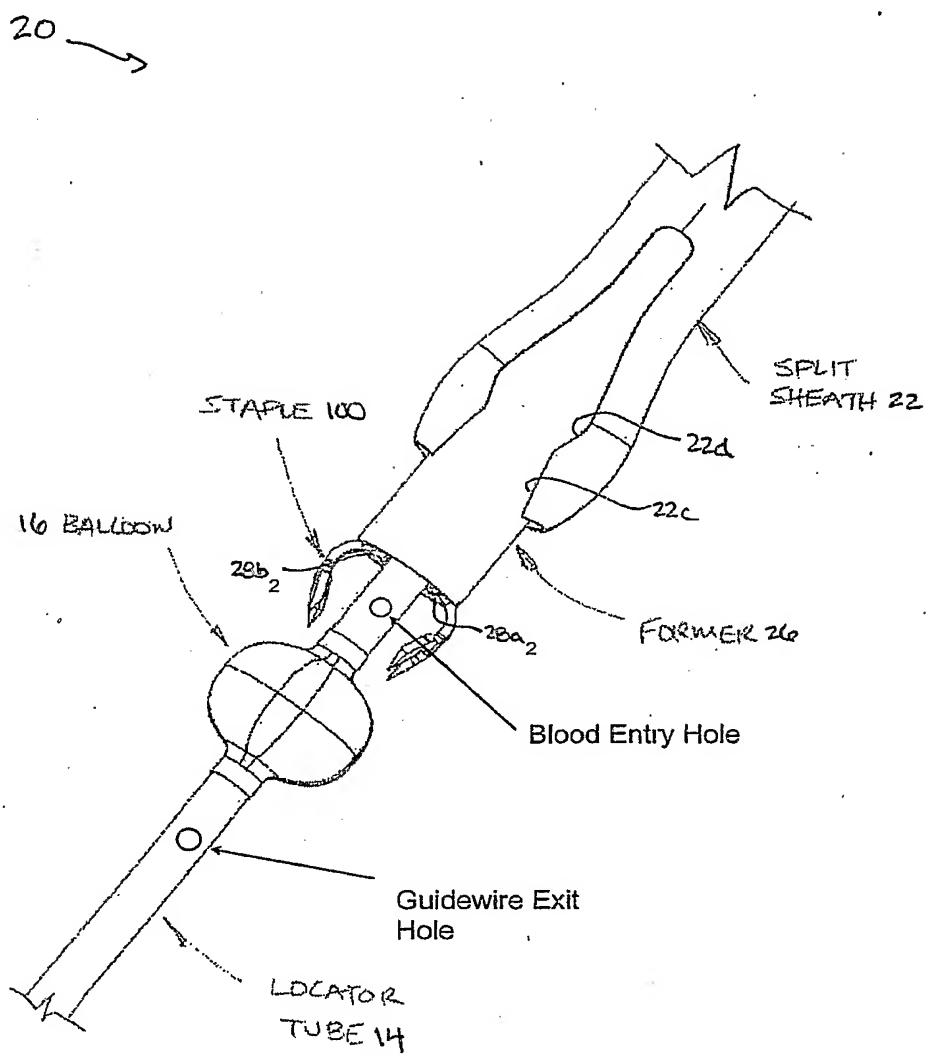


FIG 7

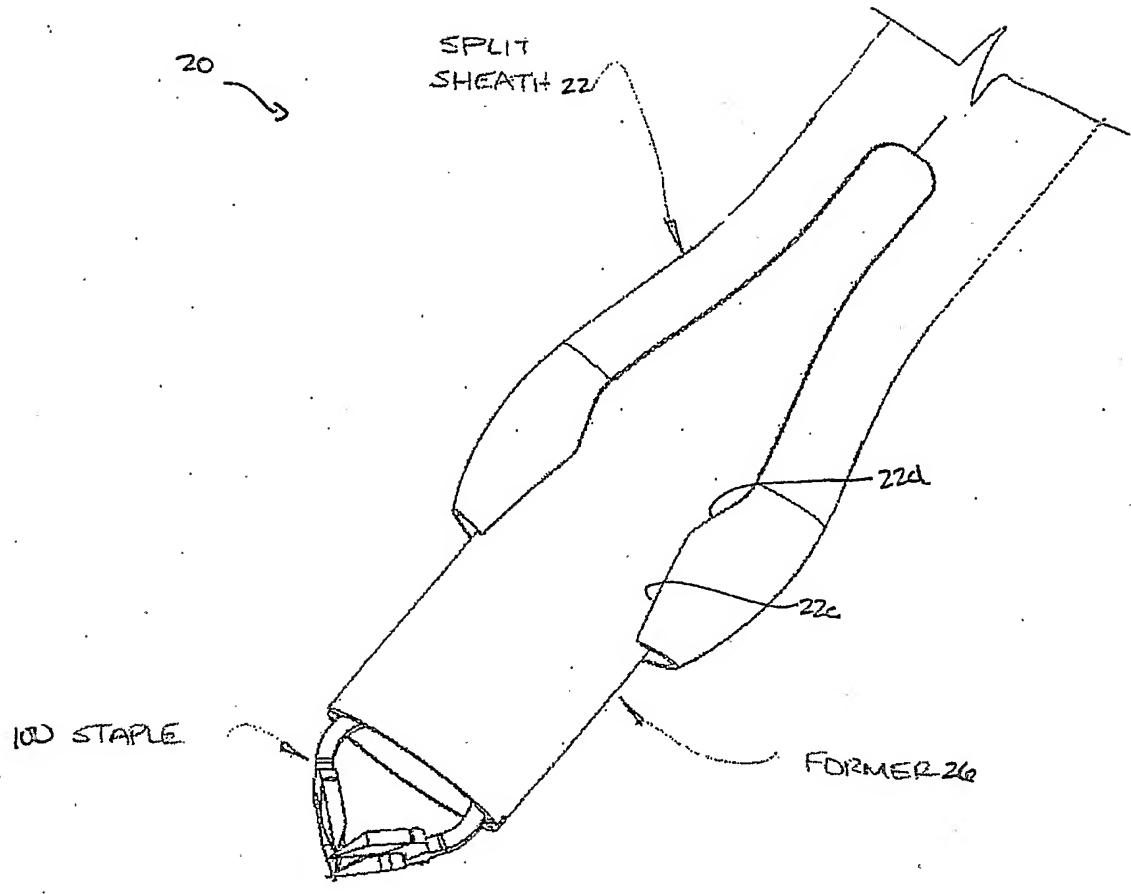


FIG. 8

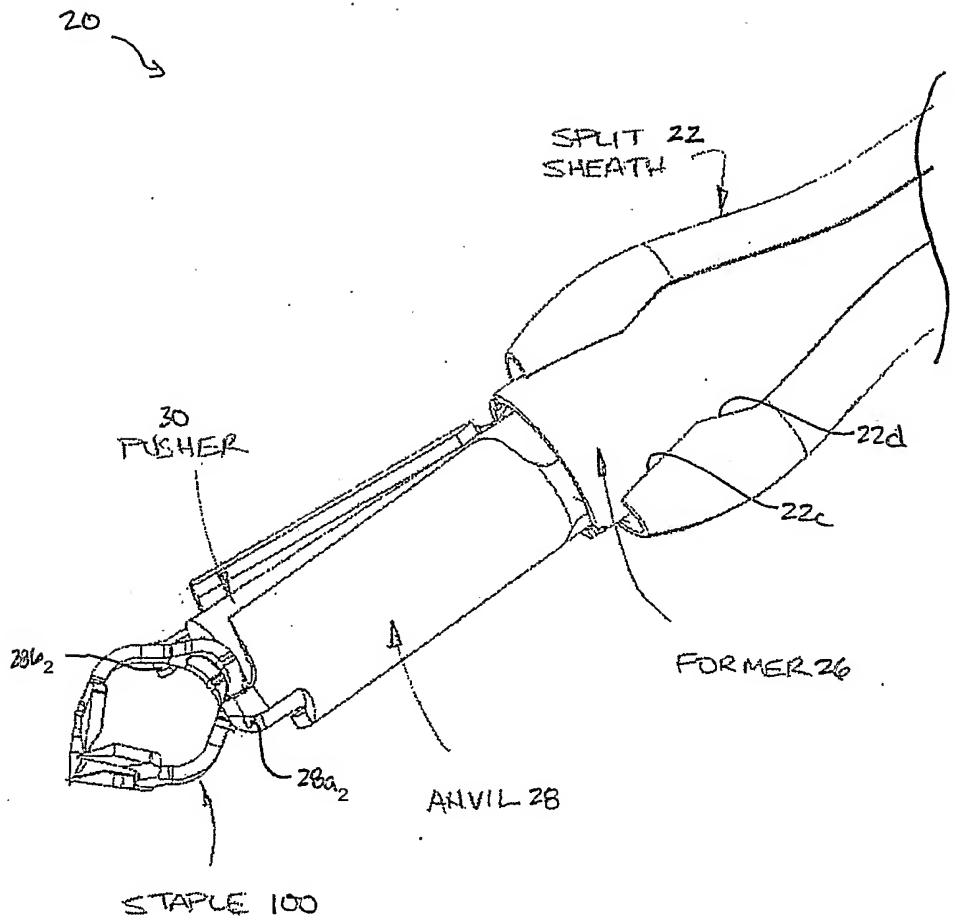


FIG. 9

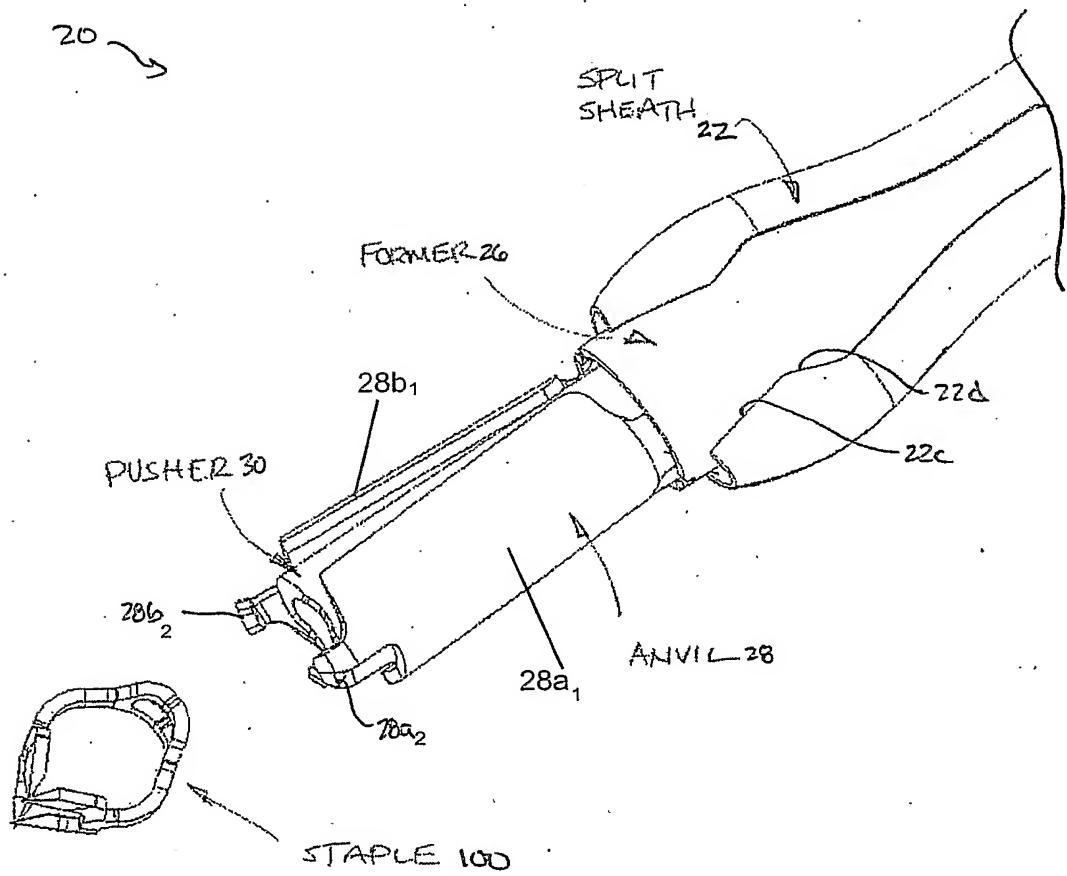


FIG. 10

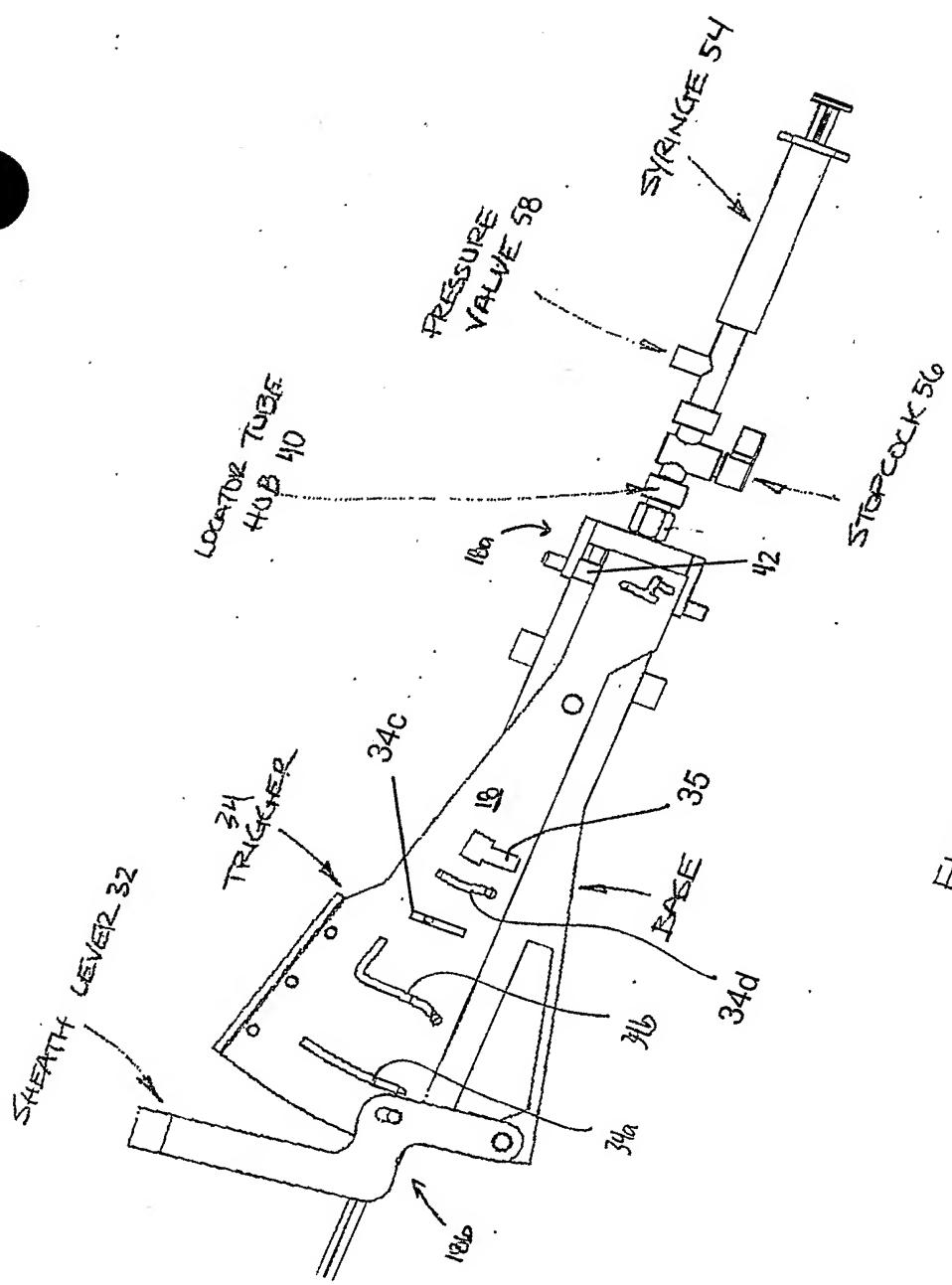


FIG. 12

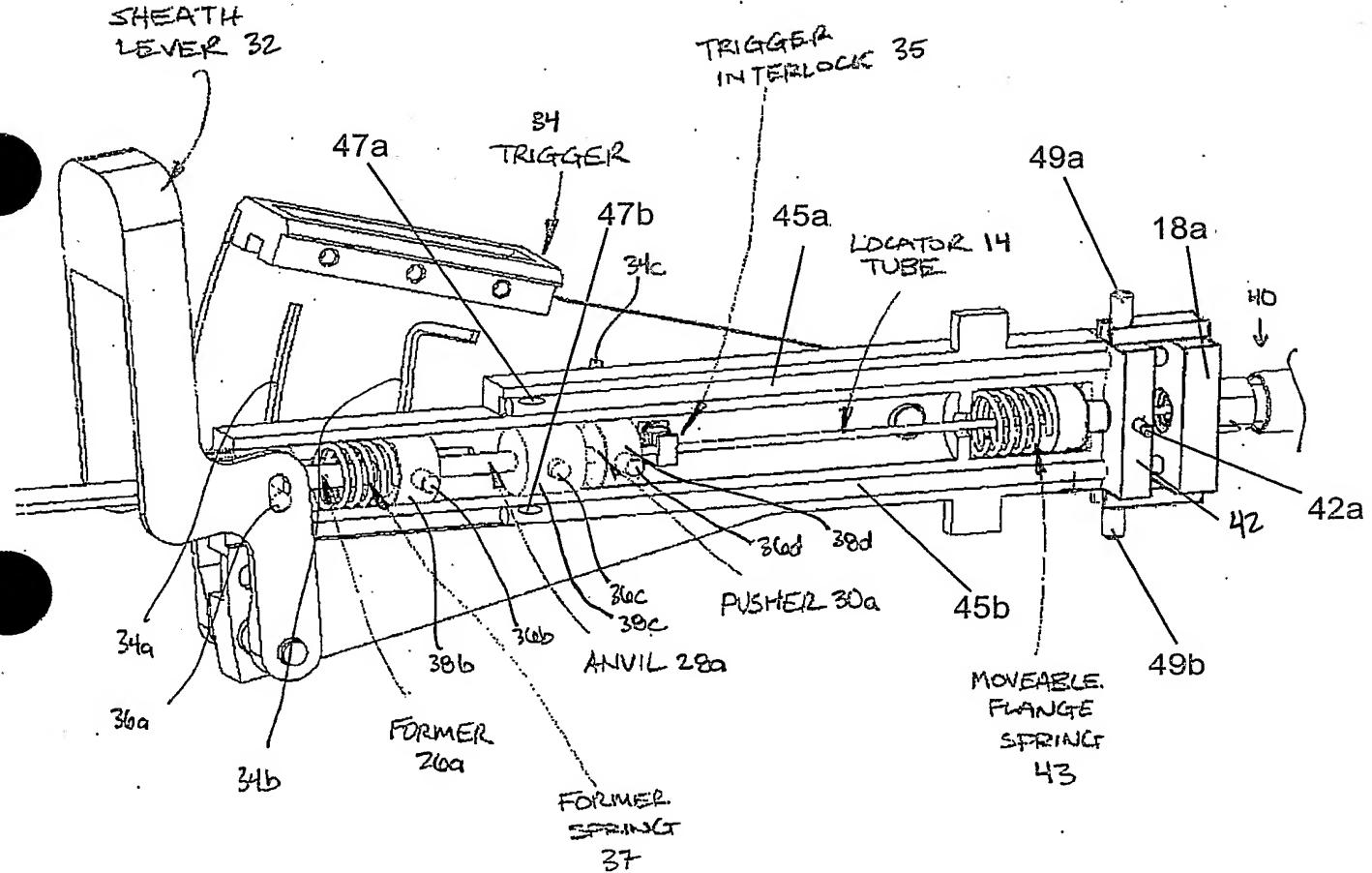


FIG. 12

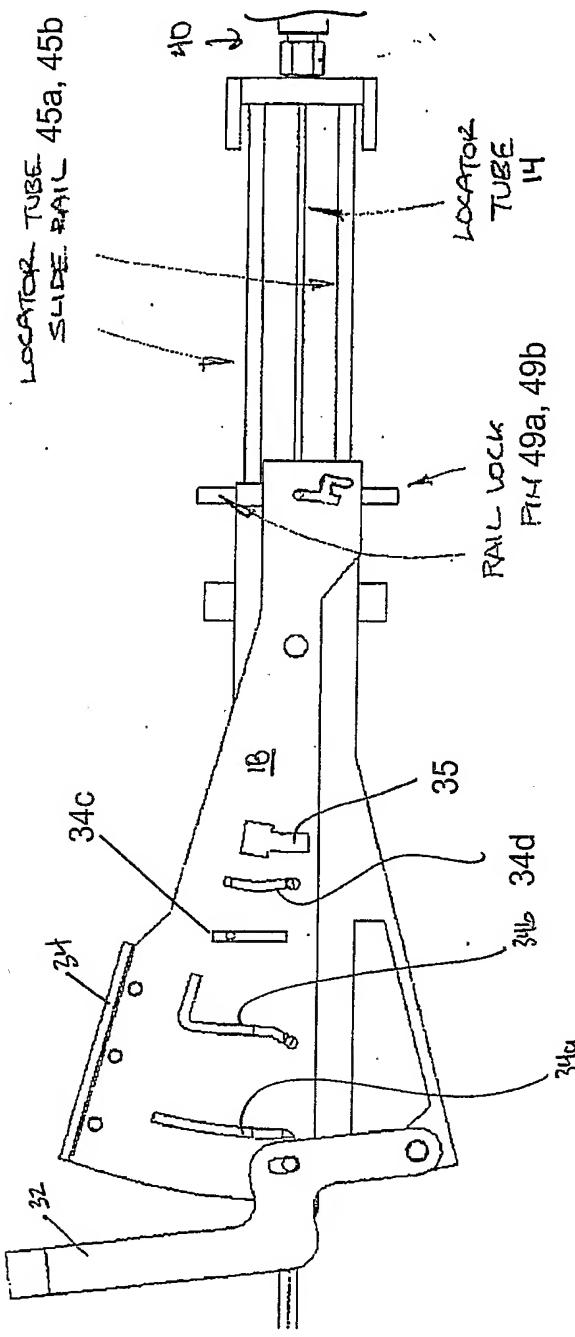
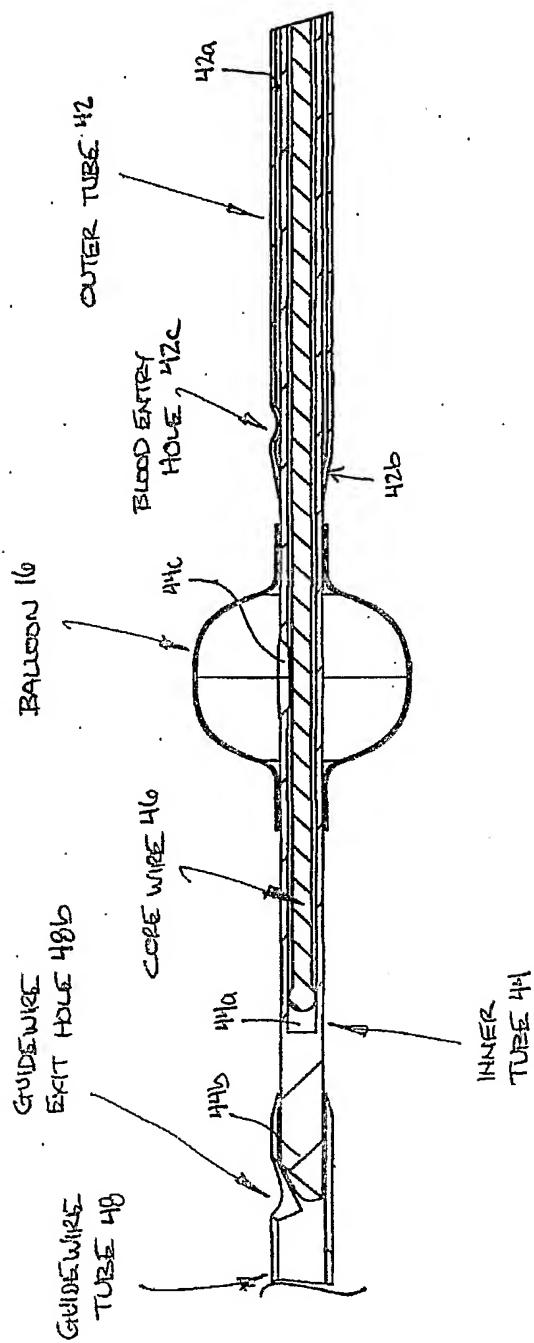


FIG. 13

FIG 14



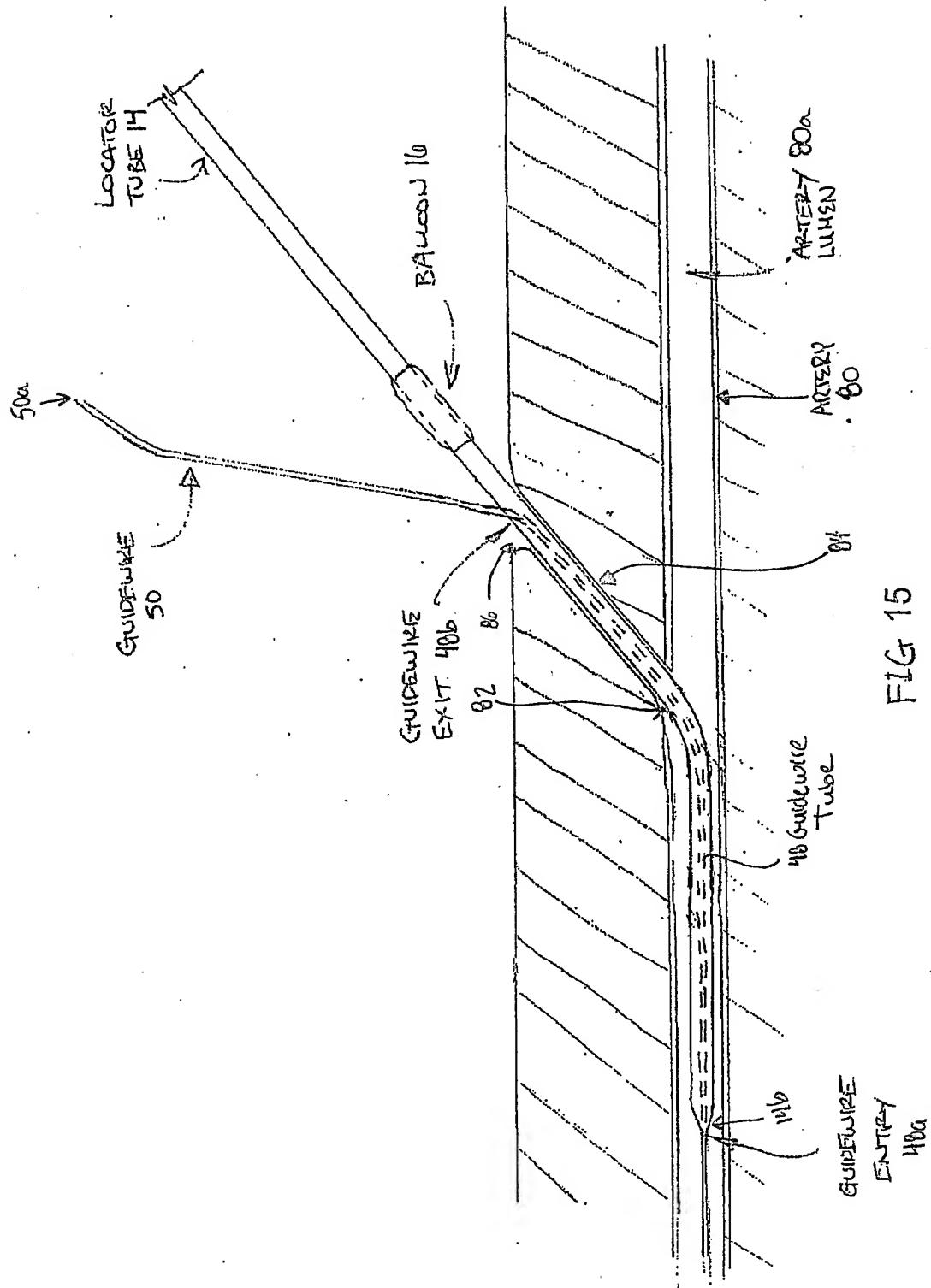


FIG 15

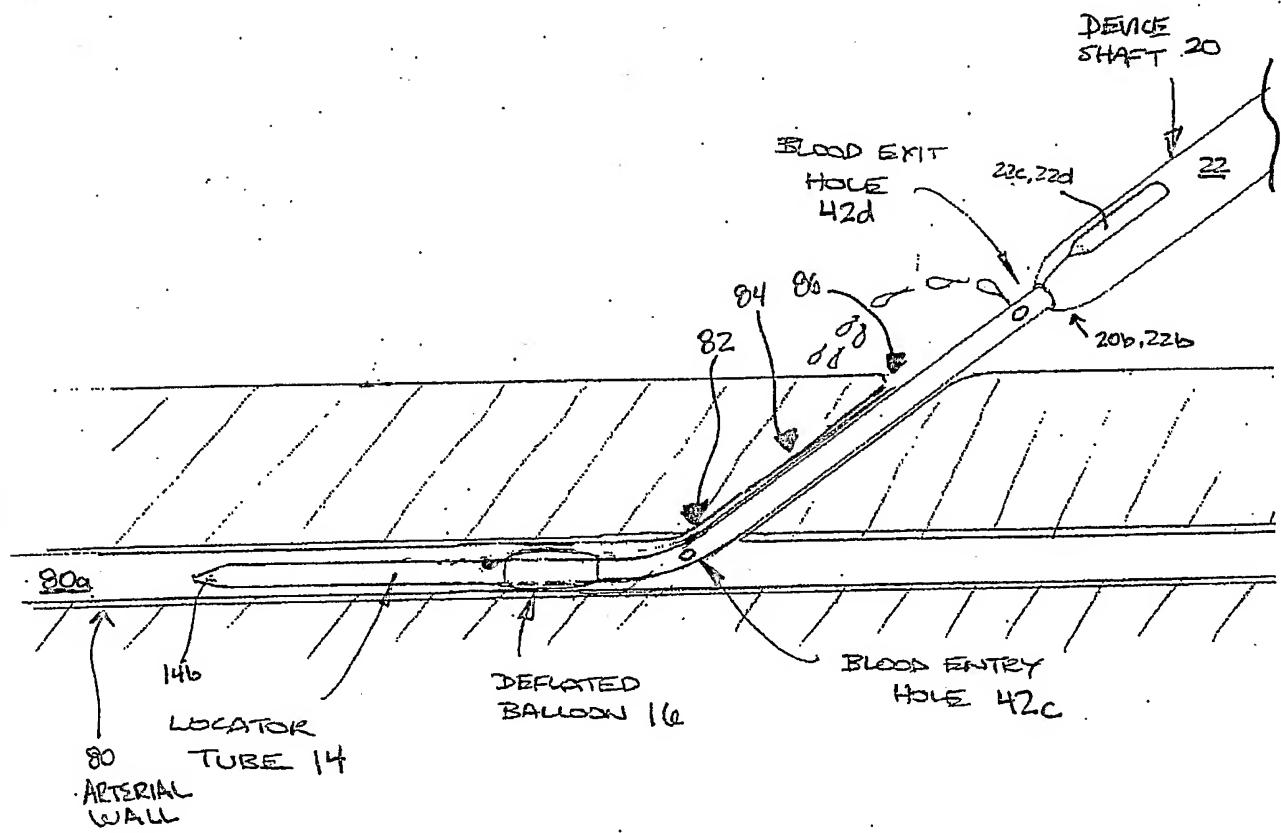


FIG 16

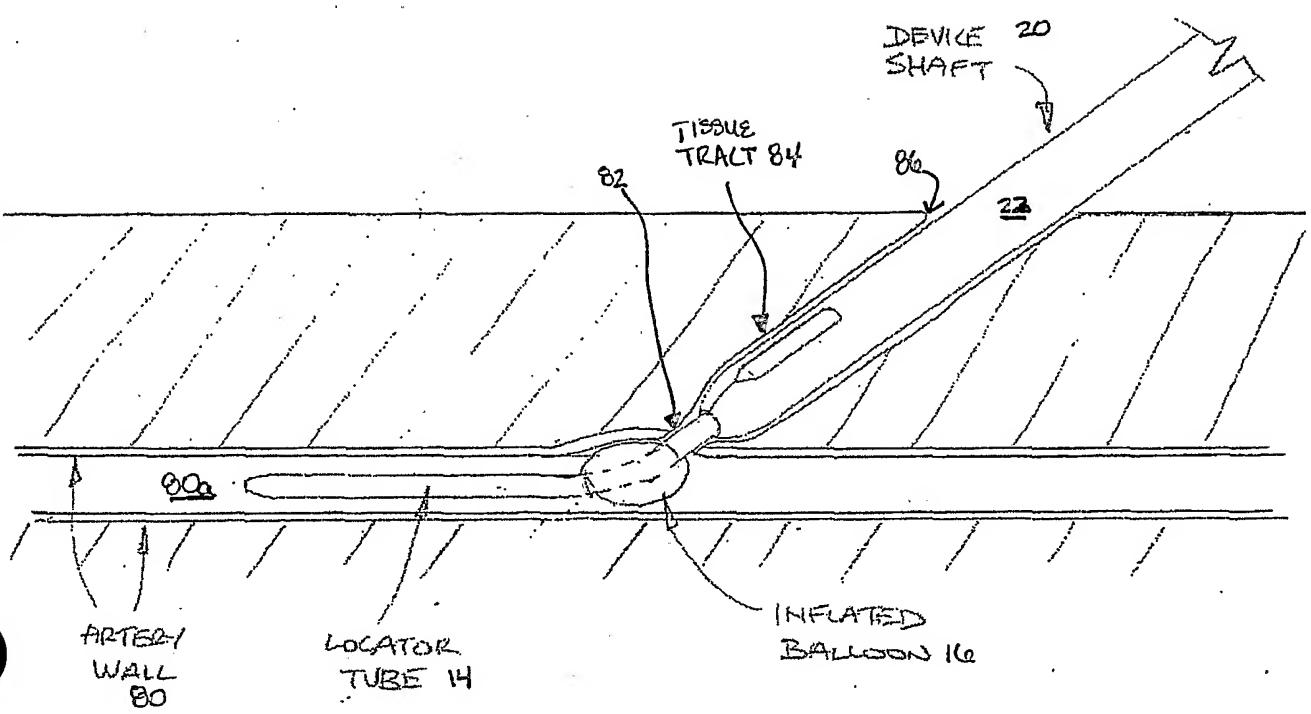


FIG. 17

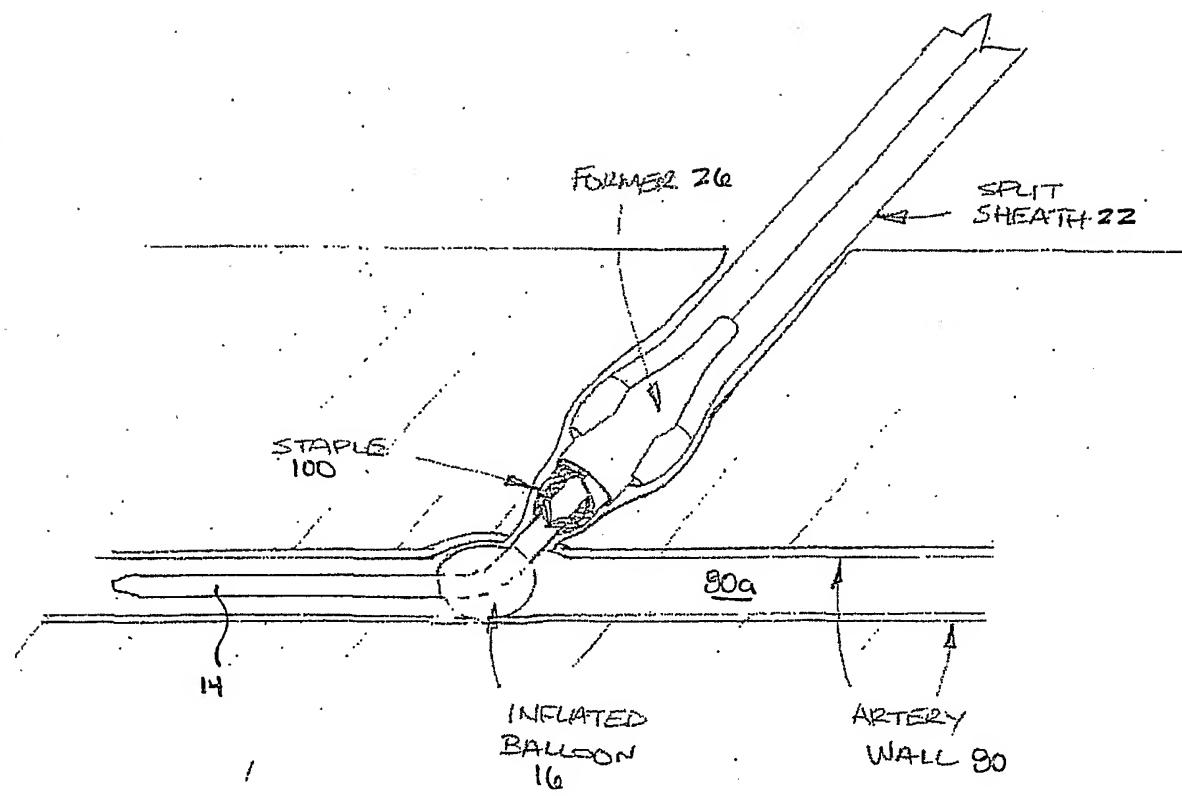


FIG. 18

FIG. 19

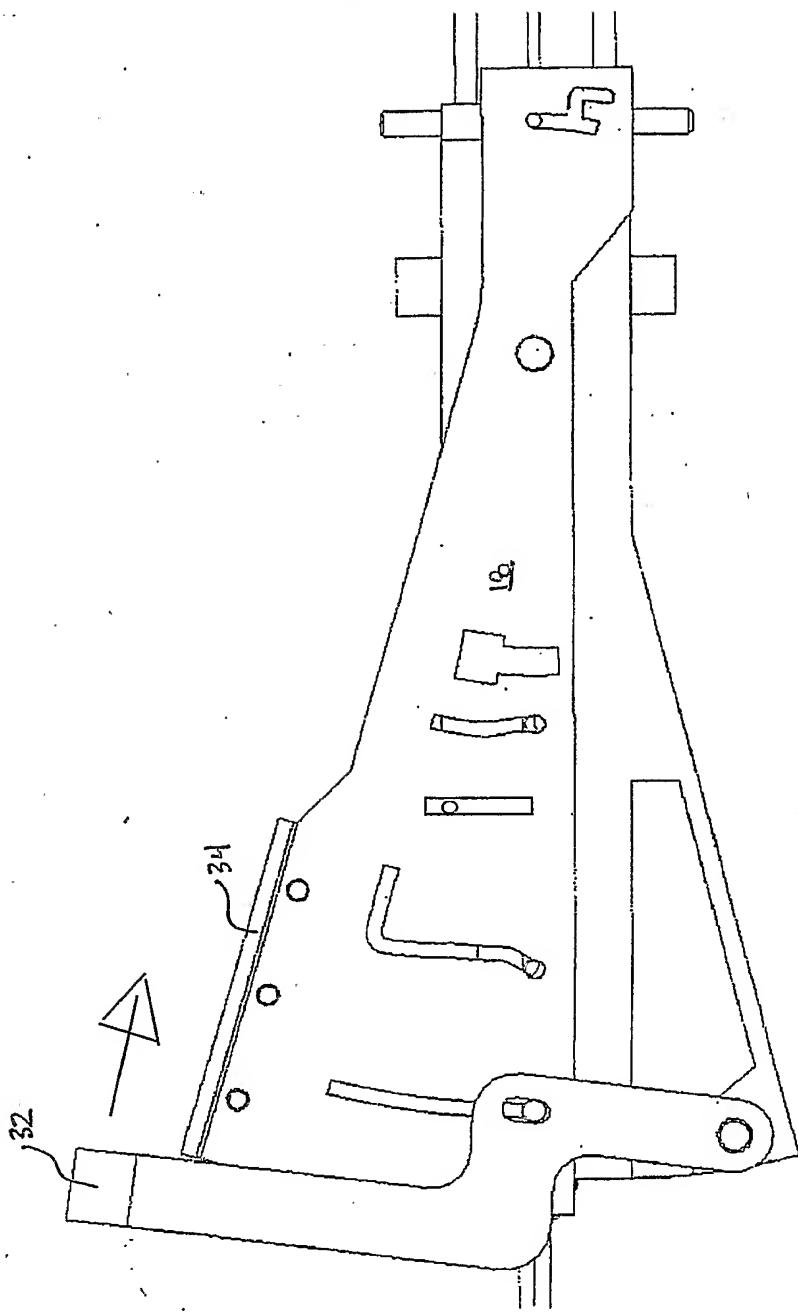
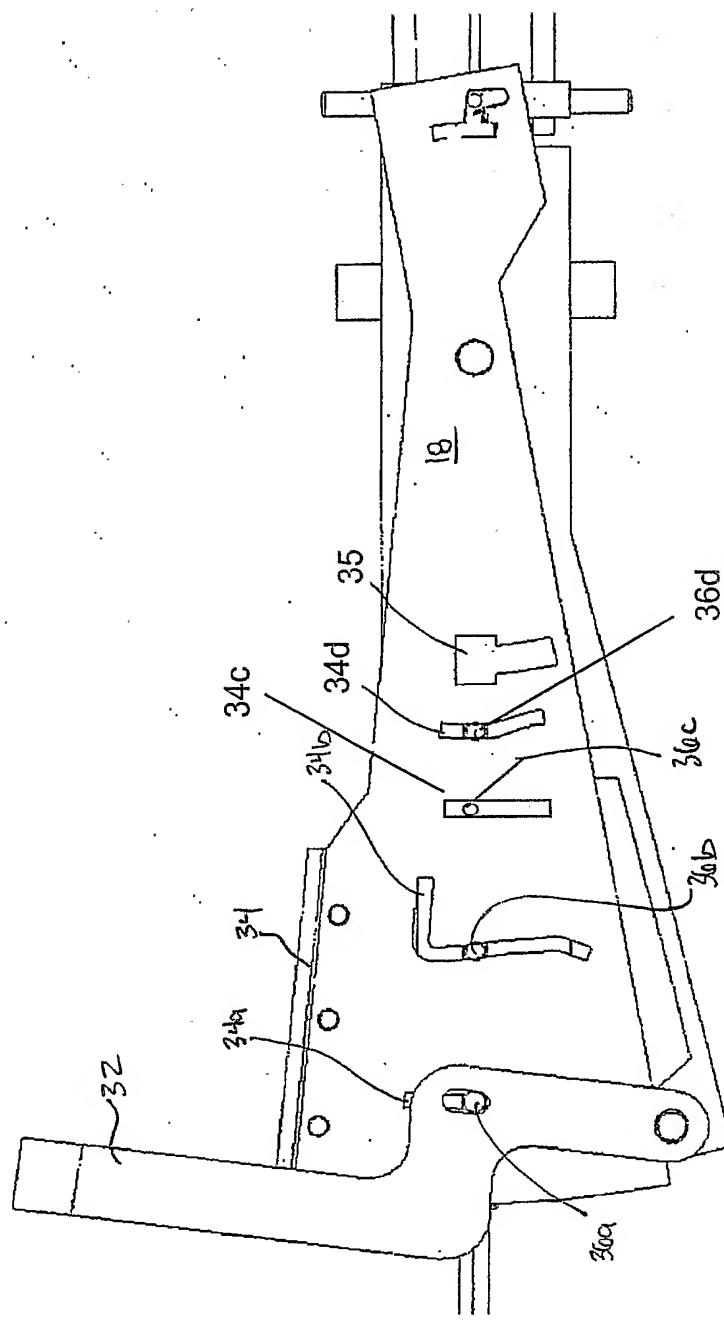


FIG. 20



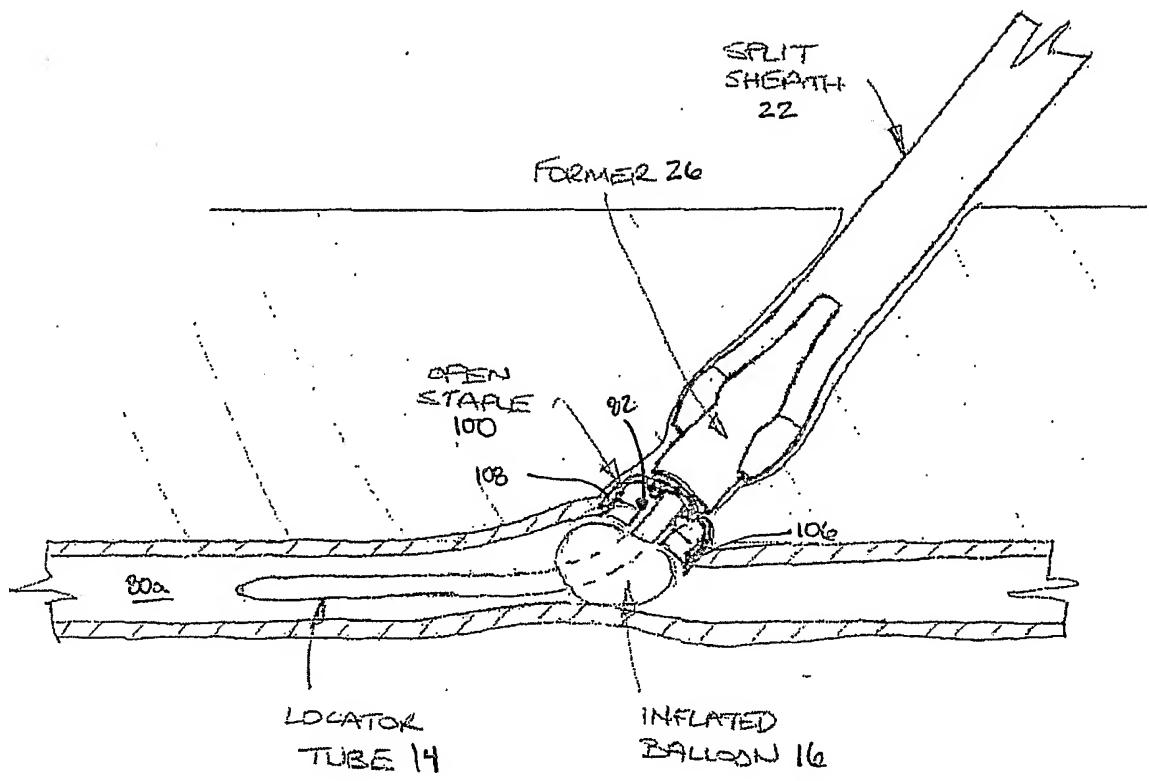


FIG. 21

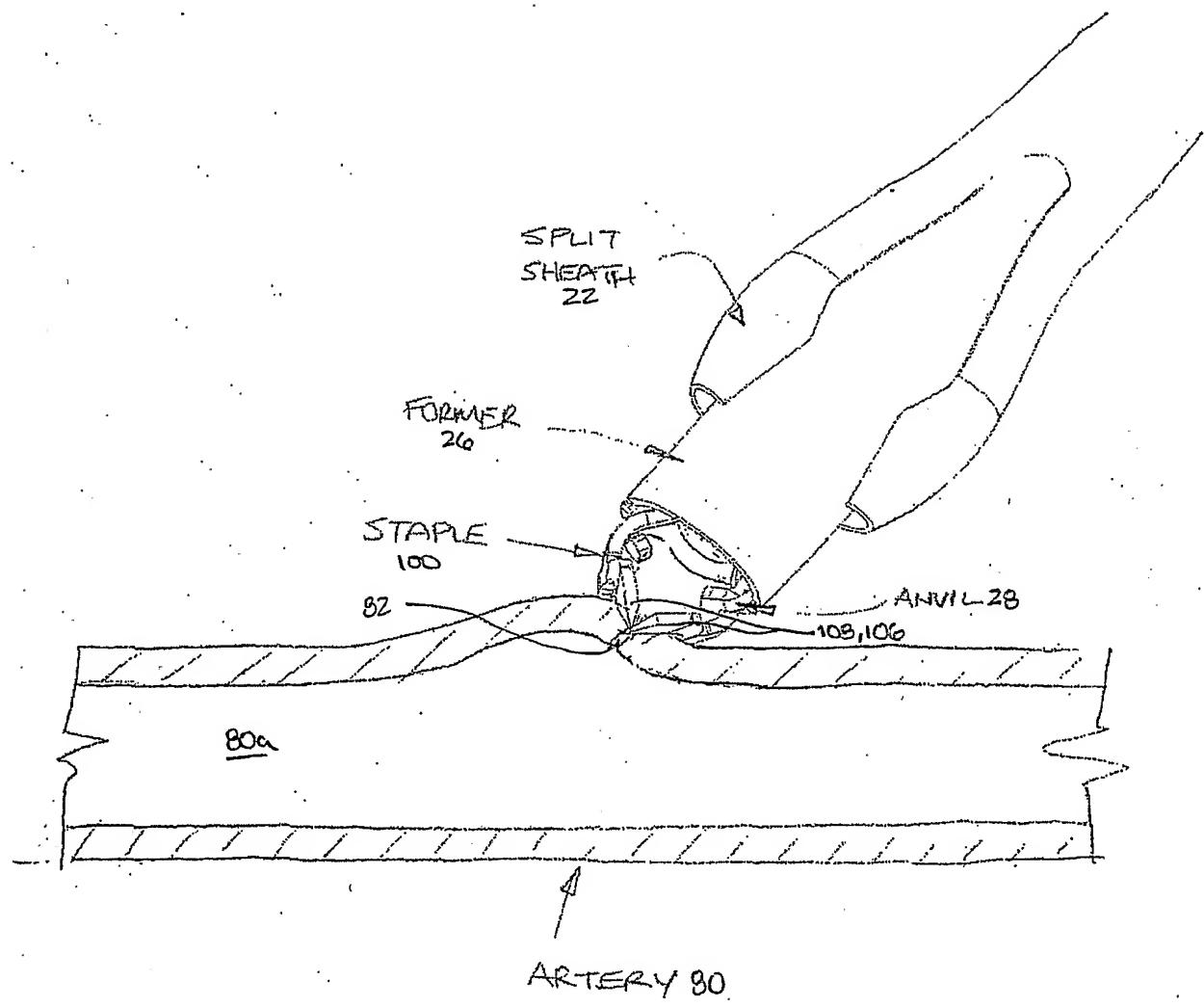


FIG. 22

FIG. 23

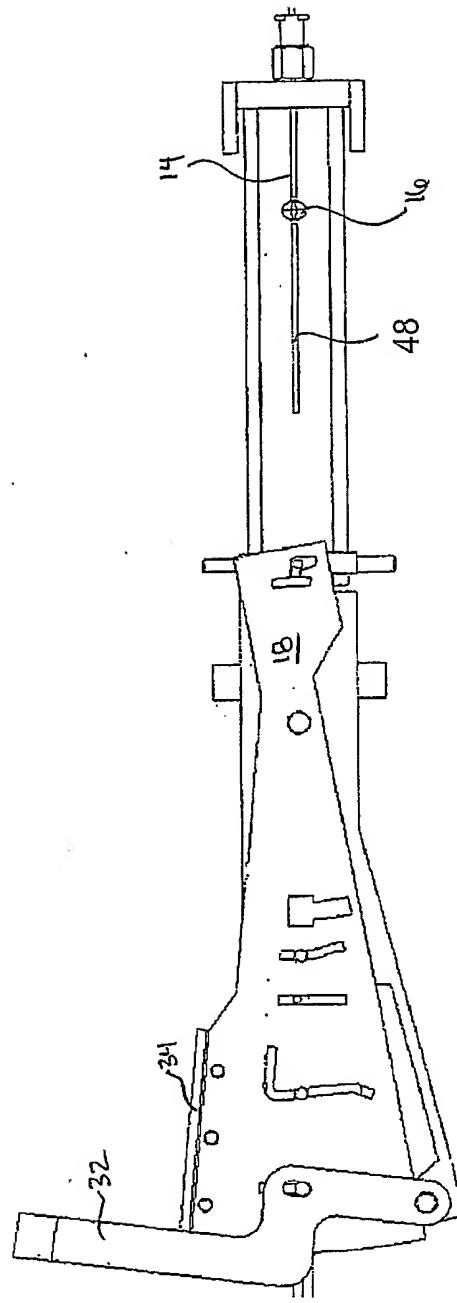
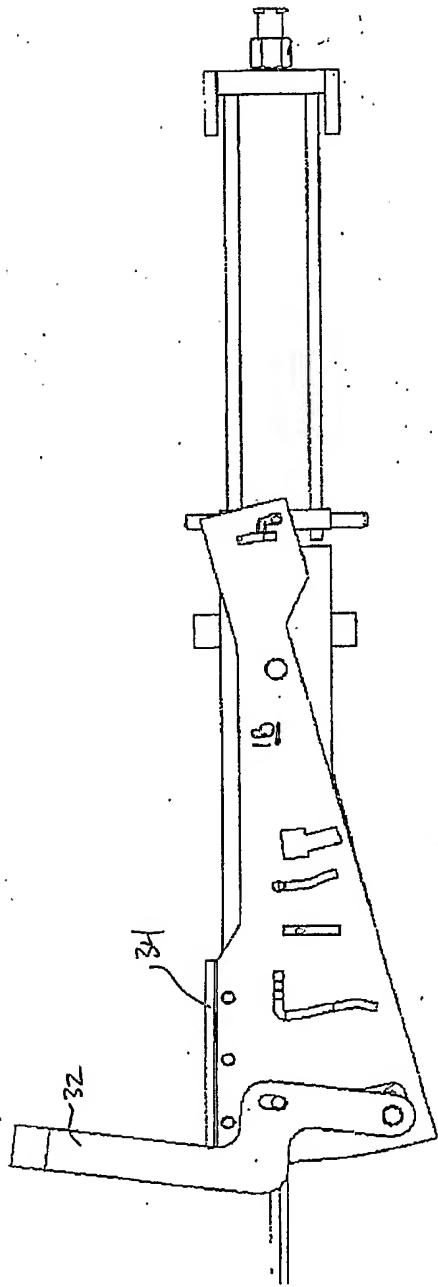


FIG. 24



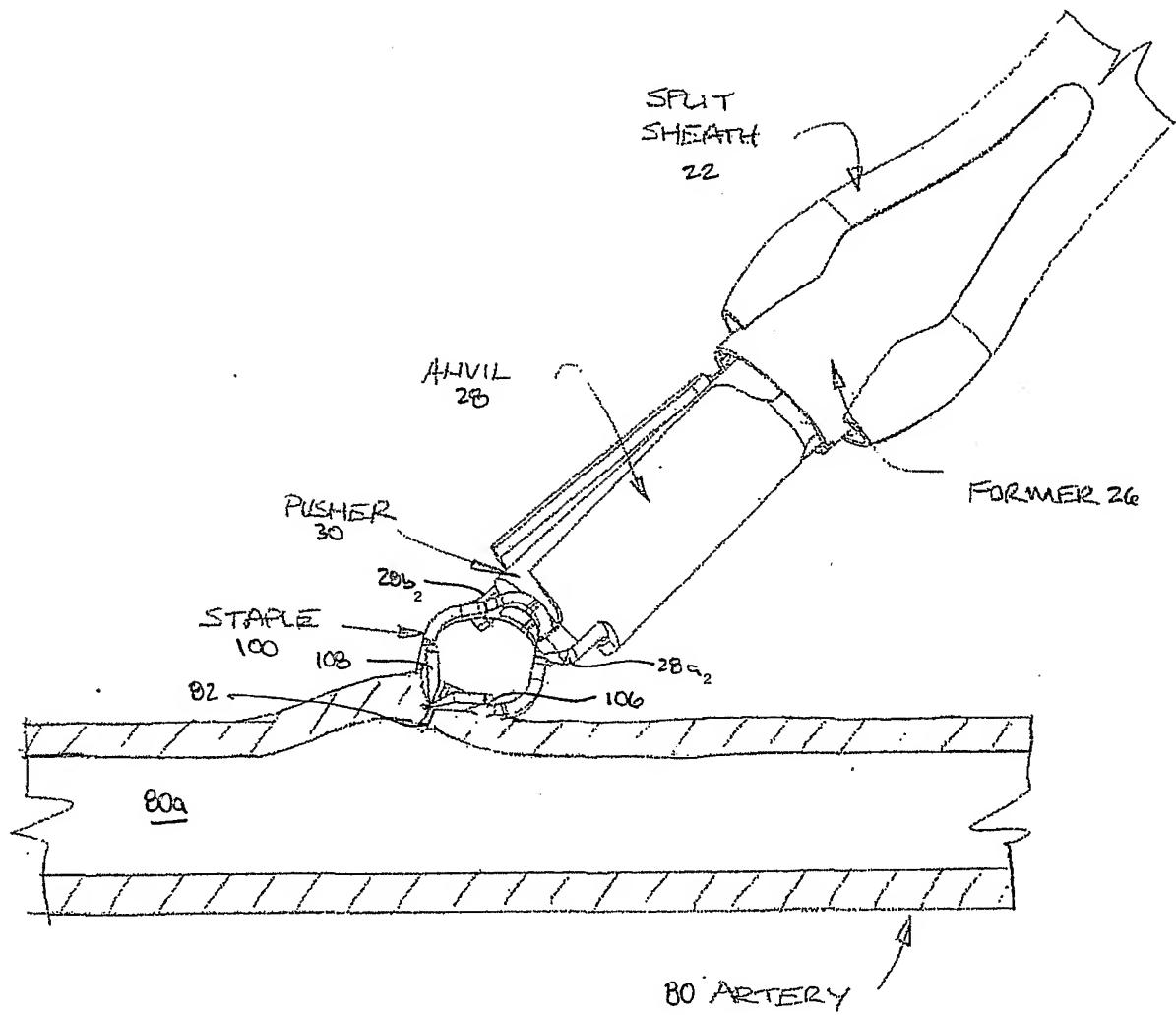


FIG 25

STAPLE 100

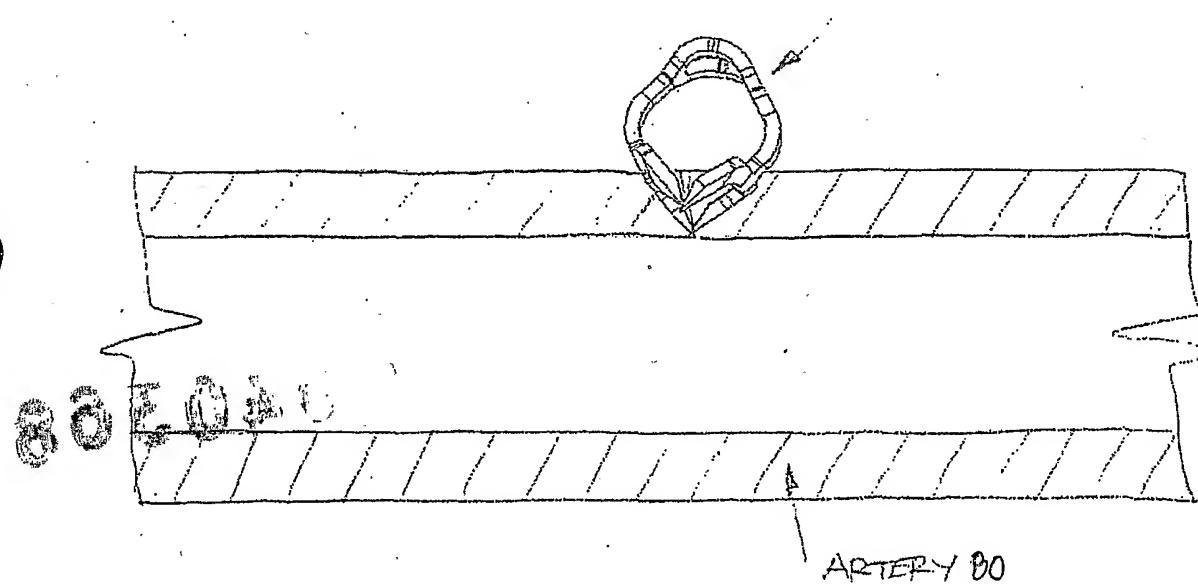


FIG. 26